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Supreme Court, U.S.
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No. ——

IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

AMERICAN DENTAL ASSOCIATION,
Petitioner,

v.

ROBERT REICH, SECRETARY OF LABOR, *et al.*,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

Section 6(b)(5) of the Occupational Safety and Health Act authorizes the Secretary of Labor to issue standards regulating harmful physical agents in the workplace. Before issuing a standard, the Secretary must make a threshold finding that workers are exposed to a significant risk of material health impairment. The standard at issue regulates occupational exposure to a variety of viral agents that may be transmitted by contact with blood or other body fluids. The questions presented are:

1) Whether the Secretary, when adopting a standard concerning a number of harmful physical agents, each of which presents different risks in the disparate industries to which the standard will apply, may assume that the risk is uniform across all industries for the purpose of making the determination that there is a significant risk of material health impairment.

2) Whether the Secretary may ignore more cost-effective alternatives to the standard adopted that would eliminate or substantially reduce the risk to workers.

3) Whether a reviewing court of appeals may defer to the Secretary's findings, though unsupported by evidence in the record, on the grounds that (a) the Court is unqualified to pass judgment on the findings, and (b) the regulated industries did not disprove the findings.

PARTIES TO THE PROCEEDING

The parties to case no. 91-3865 below were: the American Dental Association, Petitioner; Robert Reich, Secretary of Labor,* and the Occupational Safety and Health Administration, Respondents; and the American Federation of State, County and Municipal Employees, AFL-CIO, and Service Employees International Union, AFL-CIO, Intervening Respondents.

The parties to consolidated case no. 92-1482 below were: Home Health Services and Staffing Association, Inc., Petitioner; and Robert Reich, Secretary of Labor, and the Occupational Safety and Health Administration, United States Department of Labor, Respondents.

The parties before this Court are the same as the parties below.

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* Pursuant to Fed. R. App. P. 43(c)(1), Robert Reich was substituted as a Respondent upon succeeding Lynn Martin as Secretary of Labor.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED FOR REVIEW	i
PARTIES TO THE PROCEEDING	ii
TABLE OF AUTHORITIES	iv
OPINIONS BELOW	1
JURISDICTION	2
STATUTES INVOLVED	3
STATEMENT OF THE CASE	4
REASONS FOR GRANTING THE WRIT	10
I. THE COURT OF APPEALS' DECISION RAISES IMPORTANT ISSUES CONCERNING OSHA'S OBLIGATION TO FIND A SIGNIFICANT RISK OF HEALTH IMPAIRMENT BEFORE ISSUING A STANDARD, AND CONFLICTS WITH DECISIONS BY THIS COURT AND OTHER COURTS OF APPEALS	10
II. THE COURT OF APPEALS' DECISION RAISES AN IMPORTANT ISSUE CONCERNING OSHA'S AUTHORITY TO IGNORE MORE COST-EFFECTIVE ALTERNATIVES TO THE STANDARD ADOPTED	13
III. THE COURT OF APPEALS' DECISION CONFLICTS WITH DECISIONS BY THIS COURT AND OTHER COURTS OF APPEALS CONCERNING THE BURDEN OF PROOF AND STANDARD OF REVIEW	14
CONCLUSION	17

TABLE OF AUTHORITIES

Cases Page

AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir. 1992) 11, 12, 16
American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 (1981) 10, 13, 16
Buildings & Constr. Trades Dep't, AFL-CIO v. Brock, 838 F.2d 1258 (D.C. Cir. 1988) 13
Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980) 10, 11, 15
International Union, UAW v. OSHA, 938 F.2d 1310 (D.C. Cir. 1991) 11, 12
Jacobson v. Massachusetts, 197 U.S. 11 (1905) 14
Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, 503 F.2d 1155 (3d Cir. 1974), *cert. denied*, 420 U.S. 973 (1975) 16
United Steelworkers of America v. Marshall, 647 F.2d 1189 (D.C. Cir. 1980), *cert. denied sub nom., Lead Industries Ass'n v. Donovan*, 453 U.S. 913 (1981) 12, 16

Statutes

28 U.S.C. § 1254(1) 2
29 U.S.C. § 652(8) 3, 10, 13
29 U.S.C. § 654(a)(1) 5
29 U.S.C. § 655(b)(5) ..... *passim*
29 U.S.C. § 655(f) 2, 4, 8, 16
Pub. L. No. 102-141, 105 Stat. 876, § 633 (1991) 5

Other Materials

43 Fed. Reg. 27350, 27360-61 (1978) 12
54 Fed. Reg. 23042 (1989) 4
56 Fed. Reg. 64004 (Dec. 6, 1991) 2

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PETITION FOR A WRIT OF CERTIORARI

The American Dental Association ("ADA") respectfully petitions for a writ of certiorari to review the judgment and opinion of the United States Court of Appeals for the Seventh Circuit, entered in this proceeding on January 28, 1993.

OPINIONS BELOW

The Court of Appeals' opinion is reported at 984 F.2d 823 and is reprinted in the appendix ("App.") at p. 1a.

The Final Rule on Occupational Exposure to Bloodborne Pathogens, issued by the Occupational Safety and Health Administration ("OSHA"), is reported at 56 Fed. Reg. 64004, 64175 (Dec. 6, 1991). The rule is reprinted in the appendix at p. 53a.

JURISDICTION

OSHA issued the bloodborne pathogens rule on December 6, 1991 pursuant to section 6(b)(5) of the Occupational Safety and Health Act ("OSH Act"), 29 U.S.C. § 655(b)(5).

Pursuant to section 6(f) of the OSH Act, 29 U.S.C. § 655(f), the ADA petitioned for review of the rule in the Court of Appeals for the Seventh Circuit on December 19, 1991. App. 84a. On March 6, 1992, the Seventh Circuit consolidated the ADA's petition with a petition for review filed by Home Health Services and Staffing Association, Inc. ("Home Health"). App. 85a.

On January 28, 1993, the Seventh Circuit issued an opinion denying the ADA's petition and denying in part Home Health's petition. After obtaining an extension of time, App. 86a-87a, Home Health filed a petition for rehearing and suggestion for rehearing *en banc* on February 25, 1993.

On April 6, 1993, the ADA filed in this Court a protective application for extension of time to file a petition for a writ of certiorari. On April 9, Justice Stevens issued an order extending the ADA's time for filing to June 27, 1993.

The Seventh Circuit denied Home Health's petition for rehearing on May 27, 1993. App. 88a-89a.

This Court has jurisdiction to review the judgment of the Seventh Circuit pursuant to 28 U.S.C. § 1254(1).

STATUTES INVOLVED

29 U.S.C. § 652. Definitions

For the purposes of this chapter—

* * * *

(8) The term "occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

29 U.S.C. § 655. Standards

* * * *

(b) Procedure for promulgation, modification, or revocation of standards

The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

* * * *

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be ex-

pressed in terms of objective criteria and of the performance desired.

* * * *

(f) Judicial review

Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

STATEMENT OF THE CASE

On May 30, 1989, OSHA published a Notice of Proposed Rulemaking on occupational exposure to pathogens, such as the hepatitis B virus ("HBV") and the human immunodeficiency virus ("HIV"), which may be transmitted by contact with blood and other body fluids. 54 Fed. Reg. 23042 (1989). The ADA objected to the proposed rule.[1]

During the rulemaking proceedings, the ADA emphasized that dental health care workers routinely are exposed to saliva, which does not present a significant risk of HBV or HIV transmission. App. 104a. A patient's saliva may contain some quantity of blood, but the frequency and degree of exposures to blood in dental offices are far lower than in other health care settings.[2]

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[1] OSHA received over 3,000 comments on the proposed rule, resulting in the largest substantive record in OSHA's history. The ADA submitted three sets of comments, a post hearing brief, and supplementary information. *See* Record Ex. 11-43, 20-665, 58, 282, 295.

[2] Dental offices are controlled environments; more than 90% of all dental patients are seen by appointment for specific treatment.

The ADA also emphasized that the HBV vaccine, which was not available until the early 1980s, virtually eliminates the risk of hepatitis B. Record Ex. 295 at 10. HBV is the only pathogen that OSHA found presents a significant risk to worker health. App. 92a-93a.

In addition, the ADA stressed that the Centers for Disease Control and Prevention ("CDC") had issued guidelines as early as 1986 for the control of HIV and HBV transmission in health care settings. On August 15, 1988, OSHA instituted a compliance program to enforce the CDC guidelines in health care settings. OSHA used existing regulations and its statutory authority under the "general duty" clause, 29 U.S.C. § 654(a)(1), to enforce the CDC guidelines.

In 1991, the CDC issued guidelines for the control of HIV and HBV transmission in "exposure-prone invasive procedures." Among other things, those guidelines instructed health care workers to "adhere to universal precautions, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments." [3] App. 100a-102a. The guidelines state that exposure-prone procedures "should be identified by medical/surgical/dental organizations and institutions at which the procedures are performed." App. 101a.

On October 28, 1991, Congress passed a law requiring the States to adopt and enforce the 1991 CDC guidelines. *See* Pub. L. No. 102-141, 105 Stat. 876, § 633 (1991). As of June 1993, 31 states had adopted the guidelines or equivalent requirements; 19 states and the District of Columbia had sought extensions of time in which to enact the guidelines.

Record Ex. 20-665, Ref. #4, at 6. Spattering of saliva rarely occurs in dental care. Most dentists have a dental assistant using a high speed evacuator to aspirate debris from the mouth, reducing the possibility of any spattering out of the mouth. App. 96a-99a.

[3] A worker adhering to universal precautions assumes that all blood and certain other body fluids are potentially infectious for HIV, HBV and other pathogens. App. 103a.

1. *The OSHA Standard.*

OSHA promulgated the final rule on December 6, 1991. OSHA did not attempt to determine whether dental health care workers or any other discrete group of workers are exposed to a significant risk of health impairment. Instead, OSHA lumped together all affected workers for purposes of evaluating the potential risk. OSHA also made no attempt to assess whether any provision of the final rule was reasonably necessary in health care settings given enforcement of the CDC guidelines by OSHA and Congress' recent mandate to the States to enforce them.

OSHA found that HBV presents a significant risk of material health impairment to workers exposed to blood and other potentially infectious body fluids. App. 93a. However, OSHA concluded that "there are not sufficient data on HIV to quantify the occupational risk of infection." *Id.* OSHA also briefly discussed other bloodborne pathogens, such as syphilis and malaria, but did not make any risk assessment for those diseases. App. 92a. Nonetheless, OSHA concluded that the final rule would reduce the risk of those diseases. *Id.*

Unlike the CDC guidelines, which give health care professionals some discretion in choosing which precautions to observe in particular circumstances, the bloodborne pathogens rule requires across-the-board protection whenever a worker reasonably anticipates "occupational exposure to blood or other potentially infectious materials." App. 53a, § 1910.1030(a). The rule requires observance of universal precautions with respect to all potentially infectious materials, including "saliva in dental procedures." App. 55a, § (b); 58a, § (d)(1). Under the CDC guidelines, "[u]niversal precautions do not apply to saliva."[4] App. 104a. That distinction is impor-

[4] The CDC determined that "[g]eneral infection control practices already in existence . . . should further minimize *the minute risk, if any, for salivary transmission of HIV and HBV.*" App. 104a (emphasis added).

tant because nearly half of the 480 million annual patient visits expose dental health care workers to saliva without blood. Record Ex. 58.

The rule requires use of personal protective equipment, including gloves, gowns, laboratory coats, face shields or masks, and eye protection. App. 61a-62a, § (d)(3)(i). Employers must segregate and launder all contaminated personal protective equipment, at no cost to the employee. App. 62a, § (d)(3)(iv); 68a, § (d)(4)(iv).[5] Employers also must comply with provisions governing "regulated waste," which could include such items as gloves, masks, and cotton wadding. App. 56a, 67a, § (d)(4)(iii)(B).

The rule requires employers to make hepatitis B vaccinations available at no cost to all employees who have occupational exposure. App. 72a-73a, §§ (f)(1)(i), (f)(2)(i). OSHA found that the vaccine is 96% effective and that an extremely small percentage of the 4% for whom the vaccine is ineffective are at risk of hospitalization or death from HBV.[6] App. 91a. OSHA rejected a mandatory vaccination program because of privacy concerns and because mandatory HBV vaccination "would not protect workers from other bloodborne pathogens." App. 94a-95a.

The final rule has a major impact on the dental care profession. Every time a dental health care worker reasonably anticipates exposure to saliva, he or she must don protective equipment, including a protective gown, a face shield, and gloves. If the protective equipment be-

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[5] The CDC, on the other hand, has concluded that the risk of disease transmission through contact with soiled linen "*is negligible.*" App. 103a (emphasis added).

[6] OSHA concluded that only 0.043 to 0.059 per thousand workers who lack immunity would die per year from HBV, and only 0.096 to 0.134 per thousand would be hospitalized annually. App. 90a, Table V-6. Thus, in a population of one million vaccinated workers, two per year would die from hepatitis B and five year would be hospitalized.

comes soiled with saliva, the employer must comply with the rule's laundry and waste disposal requirements. These steps must be taken regardless of whether the worker reasonably anticipates exposure to blood in the patient's saliva, and regardless of whether the worker has received the HBV vaccine. The rule imposes enormous costs on the dental health care profession at a time when the federal government is considering major reforms to control the rising cost of health care.[7]

2. ***The Court of Appeals' Opinion.***

On December 19, 1991, pursuant to 29 U.S.C. § 655(f), the ADA petitioned for review of the bloodborne pathogens rule in the Court of Appeals for the Seventh Circuit. On January 28, 1993, the Seventh Circuit issued a 2-1 opinion denying the ADA's petition for review.

The panel majority acknowledged OSHA's failure to assess the potential risk to workers on an industry-by-industry basis. App. 8a. Nonetheless, the majority concluded that the risk of infection does not vary "in a readily determinable fashion from industry to industry," since "[t]he risk goes with practices." App. 9a.

The majority opinion discussed HIV and HBV together, as though both pathogens justified OSHA's decision to regulate. *E.g.*, App. 8a-9a. The majority did not mention OSHA's conclusion that there are insufficient data to quantify the occupational risk from HIV. The majority did not address (nor had OSHA considered) the possibility of promulgating different rules based upon an assessment of the risks associated with each pathogen.

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[7] The ADA estimated that the proposed rule would cost dental employers $409 million per year. Record Ex. 20-665 at 28. That is more than half of OSHA's estimated $813 million compliance cost for all affected industries.

Although the majority opinion equated the final rule with the CDC guidelines, App. 5a, 9a-10a, the majority did not discuss the impact of enforcement of the CDC guidelines on the potential risk to health care workers. The majority also did not discuss the cost-effectiveness of the final rule compared with regulatory alternatives, such as a mandatory HBV vaccination program.

The majority opinion acknowledged significant errors by OSHA with respect to the cost of the final rule and the lives and benefits lost because of the rule. App. 6a. The majority acknowledged that the final rule "may be unnecessary; it may go too far; its costs may exceed its benefits." App. 16a. The majority disregarded those errors and upheld the rule, concluding that a reviewing court merely patrols the boundary of reasonableness and the bloodborne pathogens rule "does not cross it." *Id.*[8]

The dissenting opinion noted that OSHA aggregated 24 industry sectors for purposes of determining whether HIV, HBV, and other viruses expose workers to a significant risk, and that OSHA equated exposure to blood with exposure to other body fluids that may carry pathogens. App. 20a, 22a. The dissenting opinion disagreed with the majority's conclusion that the risk to workers is the same across all industries. The dissent stressed that a hospital emergency room is quite different from a dental office. App. 23a-24a, 34a.

The dissent also discussed at length OSHA's redundant regulatory efforts, concluding that the combination of the CDC guidelines and HBV vaccinations virtually elimi-

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[8] The majority opinion suggested that the bloodborne pathogens rule has been accepted "by most health care industries." App. 16a. The majority failed to mention the Court of Appeals' refusal to allow the American College of Surgeons to file an *amicus curiae* brief in support of the ADA. The majority also failed to mention that the rule has a unique impact on dental health care workers because it treats "saliva in dental procedures" as potentially infectious material.

nates the risk to workers that OSHA found. The dissent noted that a mandatory HBV vaccination program would be far more cost-effective than the final rule:

> *For reasons unknown and contrary to sound medical judgment and research, OSHA concluded that even though vaccinations would reduce almost all risk of health care professionals becoming infected by HBV, the additional, far more expensive, impractical and cost inefficient precautions were necessary.*

App. 33a (emphasis in original).

REASONS FOR GRANTING THE WRIT

I. THE COURT OF APPEALS' DECISION RAISES IMPORTANT ISSUES CONCERNING OSHA'S OBLIGATION TO FIND A SIGNIFICANT RISK OF HEALTH IMPAIRMENT BEFORE ISSUING A STANDARD, AND CONFLICTS WITH DECISIONS BY THIS COURT AND OTHER COURTS OF APPEALS.

A. This Court has interpreted section 3(8) of the OSH Act, 29 U.S.C. § 652(8), to require OSHA, before it issues a standard under section 6(b)(5), to make threshold determinations (1) that a harmful physical agent poses a significant risk of material health impairment at existing worker exposure levels, and (2) that a new OSHA standard will substantially reduce the risk. *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 641-42 (1980) (hereinafter, *"Benzene"*); *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 506-507 (1981) (hereinafter, *"Cotton Dust"*).

The Court of Appeals' majority opinion effectively held that OSHA may make those determinations in a vacuum, ignoring existing regulations that reduce the risk to workers. When it adopted the bloodborne pathogens rule, OSHA knew the CDC guidelines, as enforced by OSHA and the States, would reduce the risk to health care

workers from exposure to HBV. Nonetheless, OSHA made no effort to ascertain the level of risk that remained or to quantify any additional margin of safety provided by the rule.

The majority opinion silently endorsed OSHA's failure to consider existing efforts to reduce occupational risk from pathogens. The majority opinion is inconsistent with this Court's holding in *Benzene* that OSHA must find a significant risk facing workers before issuing a new standard. *See* 448 U.S. at 641-42. This Court should grant the ADA's petition for certiorari to clarify that OSHA must consider existing controls before imposing costly and burdensome new requirements on industry.

B. The majority opinion also conflicts with opinions by other courts of appeals which hold that OSHA may not lump together diverse industries and harmful physical agents for purposes of determining whether workers are exposed to a significant risk. In *AFL-CIO v. OSHA*, 965 F.2d 962 (11th Cir. 1992), the Eleventh Circuit reviewed an OSHA air contaminants standard regulating worker exposures to 428 toxic substances. Noting the lack of risk information OSHA supplied with respect to the individual substances, *id.* at 975-76, the Eleventh Circuit set aside the standard, concluding that OSHA had "lumped together substances and affected industries and provided such inadequate explanation that it is virtually impossible for a reviewing court to determine if sufficient evidence supports the agency's conclusions." *Id.* at 986.

Similarly, in *International Union, UAW v. OSHA*, 938 F.2d 1310 (D.C. Cir. 1991), the District of Columbia Circuit reviewed an OSHA rule requiring workers in almost all industries to lock out energy sources when servicing equipment. OSHA did not assess the level of risk within discrete subdivisions of industry, choosing instead to make a global determination that workers were exposed to a significant risk. Noting that "[j]ust because paper mill equipment . . . poses a significant hazard does

not mean that sewing machines do," and that there were "no obvious barriers to disaggregation," the D.C. Circuit remanded the standard to OSHA. *Id.* at 1322.

In this case, the majority opinion held that OSHA may generically assess the risk posed by a variety of viruses, each of which presents different risks in the diverse industries to which the bloodborne pathogens rule applies. OSHA designed the rule to protect workers against all pathogens, including HIV, though OSHA made the requisite finding of significant risk with respect to HBV only. OSHA tipped its hand in its discussion of a mandatory HBV vaccination program, which OSHA dismissed because it "would not protect workers from other bloodborne pathogens." App. 94a. The majority opinion enables OSHA to bootstrap a standard for any harmful physical agent, regardless of the risk presented by that agent, onto a standard for some other agent.

The panel majority believed that aggregation of 24 industry sectors was appropriate because the risk presented to workers was essentially the same from one industry to another. App. 9a. The majority ignored the obvious differences between exposures to blood in hospital emergency rooms and surgery wards and exposures to saliva in dental offices.

OSHA previously has disaggregated industries in rulemaking proceedings for purposes of analyzing the risk to workers. *E.g.*, 43 Fed. Reg. 27350, 27355-61 (1978) (final cotton dust standard). Moreover, the courts of appeals consistently have required OSHA to assess the feasibility of section 6(b)(5) standards on an industry-by-industry basis. *See, e.g., AFL-CIO v. OSHA*, 965 F.2d at 980; *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1277, 1301 (D.C. Cir. 1980), *cert. denied sub nom., Lead Indus. Ass'n v. Donovan*, 453 U.S. 913 (1981). OSHA should be required to take the same approach with respect to risk assessment.

The split in the courts of appeals raises a fundamental issue concerning OSHA's obligation to make a threshold finding that workers are exposed to a significant risk. Under section 6(b)(5), the significant risk determination is crucial because it triggers the regulatory process. Once OSHA finds a significant risk, it is required to adopt a feasible standard that will abate the risk. *See Cotton Dust*, 452 U.S. at 508-509. This Court should grant the ADA's petition to clarify the extent of OSHA's obligation to assess the risk presented by individual substances to workers in discrete industries.

II. THE COURT OF APPEALS' DECISION RAISES AN IMPORTANT ISSUE CONCERNING OSHA'S AUTHORITY TO IGNORE MORE COST-EFFECTIVE ALTERNATIVES TO THE STANDARD ADOPTED.

Having found that HBV (but not HIV) presents a significant risk to worker health, OSHA proceeded to adopt across-the-board restrictions on the practice of dentistry. OSHA made no attempt, however, to determine whether the rule's requirements are cost-effective when compared to regulatory alternatives, as the decision in *Cotton Dust* appears to require.[9]

The ADA argued before OSHA and the Court of Appeals that the combination of HBV vaccination and

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[9] "[I]f the use of one respirator would achieve the same reduction in health risk as the use of five, the use of five respirators was 'technologically and economically feasible,' and OSHA thus insisted on the use of five, then the 'reasonably necessary or appropriate' limitation [of § 3(8)] might come into play as an additional restriction on OSHA to chose the one-respirator standard. In this case we need not decide all the applications that § 3(8) might have, either alone or together with § 6(b)(5)." 452 U.S. at 513-14 n.32.

Cf. Building & Constr. Trades Dep't, AFL-CIO v. Brock, 838 F.2d 1258, 1269 (D.C. Cir. 1988): "As between saving lives expensively and thriftily, it would seem curmudgeonly and wasteful in the extreme (*i.e.*, not 'reasonably necessary') to insist on the former. We need not, however, resolve the issue."

enforcement of the CDC guidelines obviated any need for more comprehensive regulation by OSHA; at most, OSHA should have required vaccination of health care workers with occupational exposure to HBV. A mandatory vaccination program would virtually eliminate the risk of HBV, which is the sole justification for the final rule. OSHA refused to adopt a mandatory vaccination rule, opting instead to require a panoply of extreme precautions for all workers, whether or not they have been vaccinated.[10]

That approach might have made sense if OSHA found that HIV or other pathogens for which there are no vaccines pose a significant risk to worker health. But OSHA did not quantify the risk of HIV and did not attempt to quantify the risk associated with other pathogens. The final rule thus protects the minute percentage of workers for whom the vaccine is ineffective and those who refuse inoculation.

This Court should grant the ADA's petition to provide additional guidance concerning the limits of OSHA's authority to impose on industry costly and burdensome requirements when available alternatives are far more cost-effective.

III. THE MAJORITY OPINION CONFLICTS WITH DECISIONS BY THIS COURT AND OTHER COURTS OF APPEALS CONCERNING THE BURDEN OF PROOF AND STANDARD OF REVIEW.

The Court of Appeals' majority opinion took a hands off approach to the bloodborne pathogens rule. Characterizing themselves as "the nonspecialist, biomedically unsophisticated Article III judiciary," App. 10a, the panel majority repeatedly deferred to OSHA despite reserva-

[10] OSHA had authority to adopt a mandatory vaccination program. *See Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (vaccination can be required notwithstanding religious and privacy objections).

tions about OSHA's findings. For example, the majority opinion agreed with the ADA that:

- OSHA's estimate of the cost of compliance with the final rule "[n]o doubt . . . is an underestimate" (App. 6a);

- OSHA "exaggerated the number of lives likely to be saved by the rule by ignoring lives likely to be sacrificed by it, since the increased cost of medical care, to the extent passed on to consumers, will reduce the demand for medical care, and some people will lose their lives as a result" (*id.*);

- OSHA ignored the impact of the final rule on the quality of dental care—"the higher price of dentistry that is a likely consequence of the rule will have a greater impact on demand; and inadequate dental care is a source of pain and suffering" (App. 9a-10a).

The majority opinion further agreed that the final rule "may be unnecessary; it may go too far; its costs may exceed its benefits." App. 16a. Nonetheless, the majority deferred totally to OSHA, concluding that "we cannot resolve our doubts against the agency." App. 6a.

The majority opinion's rationale is wrong in two respects. First, it improperly places the burden of proof on the ADA. OSHA bears the burden of proof in rulemaking proceedings under section 6(b)(5). *Benzene*, 448 U.S. at 653. A reviewing court cannot accept OSHA's findings, which the court concedes are erroneous or unfounded, merely because an industry petitioner does not prove that the rule will have disastrous consequences.

Second, the majority opinion's description of the court's role on review conflicts with decisions by other courts of appeals. With respect to central issues such as the cost of the final rule and the net impact of the rule on health and safety, OSHA must find "substantial evidence in the

record considered as a whole" to justify the rule.[11] *See* 29 U.S.C. § 655(f). The substantial evidence test requires OSHA "to identify relevant factual evidence, to explain the logic and the policies underlying any legislative choice, to state candidly any assumptions on which it relies, and to present its reasons for rejecting significant contrary evidence and argument." *United Steelworkers of America v. Marshall,* 647 F.2d at 1207. *See also Synthetic Organic Chemical Mfrs. Ass'n v. Brennan,* 503 F.2d 1155, 1160 (3d Cir. 1974), *cert. denied,* 420 U.S. 973 (1975). "Considering the record 'as a whole' further requires that reviewing courts 'take into account not just evidence that supports the aegncy's decision, but also countervailing evidence.' " *AFL-CIO v. OSHA,* 965 F.2d at 970 (quoting *AFL-CIO v. Marshall,* 617 F.2d 636, 649 n.44 (D.C. Cir. 1979)).

The majority opinion did not probe the record to find evidence supporting OSHA's determinations. Faced with issues that OSHA either did not address, such as the impact of the rule on patients, or did not support with evidence in the record, such as the cost of compliance, the majority deferred to OSHA, claiming that Article III judges are unqualified to pass judgment on "technical" issues. App. 10a. The majority opinion establishes a high water mark for deference to an agency that did not do its job.

Because the majority opinion improperly shifted the burden of proof to the ADA, and because the majority opinion splits with other courts of appeals concerning the meaning and application of the substantial evidence test, this Court should grant the ADA's petition to clarify the scope of review in OSHA rulemaking proceedings.

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[11] "Substantial evidence" is " 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.' " *Cotton Dust,* 452 U.S. at 522 (quoting *Universal Camera Corp. v. NLRB,* 340 U.S. 474, 477 (1951)).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

TABLE OF CONTENTS FOR APPENDIX

	Page
Opinion of the U.S. Court of Appeals for the Seventh Circuit (Jan. 28, 1993)	1a
OSHA's Final Rule on Occupational Exposure to Bloodborne Pathogens, 56 Fed. Reg. 64004, 64175 (Dec. 6, 1991)	53a
ADA's Petition for Review, U.S. Court of Appeals for the Seventh Circuit (Dec. 16, 1991)	84a
Order Consolidating Petitions for Review, U.S. Court of Appeals for the Seventh Circuit (March 6, 1992)	85a
Order Granting Motion for Extension of Time to File Petition for Rehearing, U.S. Court of Appeals for the Seventh Circuit (Feb. 10, 1993)	86a
Order Denying Petition for Rehearing, U.S. Court of Appeals for the Seventh Circuit (May 27, 1993)	88a
Excerpts from the Preamble to the Final Rule on Occupational Exposure to Bloodborne Pathogens, 56 Fed. Reg. 64004 (Dec. 6, 1991)	90a
Excerpts from Transcripts of OSHA Rulemaking Hearings	96a
CDC, *Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures*, 40 MMWR 1, 5-6 (1991)	100a
CDC, *Recommendations for Prevention of HIV Transmission in Health-Care Settings*, 36 MMWR 3S, 5S, 11S-12S (1987)	103a
CDC, *Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings*, 37 MMWR 377, 379 (1988)	104a

APPENDIX

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

Nos. 91-3865, 92-1482

AMERICAN DENTAL ASSOCIATION and HOME HEALTH SERVICES AND STAFFING ASSOCIATION, INCORPORATED,
Petitioners,

v.

LYNN MARTIN, SECRETARY OF LABOR, and OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, UNITED STATES DEPARTMENT OF LABOR,
Respondents,

and (in No. 91-3865)

AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, AFL-CIO, and SERVICE EMPLOYEES INTERNATIONAL UNION, AFL-CIO,
Intervening-Respondents.

Petitions for Review of an Order of the
Occupational Safety and Health Administration

ARGUED JUNE 10, 1992—DECIDED JANUARY 28, 1993

Before POSNER, COFFEY, and EASTERBROOK, *Circuit Judges.*

POSNER, *Circuit Judge.* In 1991 the Occupational Safety and Health Administration promulgated a rule on occupational exposure to bloodborne pathogens. 56 Fed. Reg. 64004, 57 Fed. Reg. 29206, 29 C.F.R. § 1910.1030. The rule is designed to protect health care workers from viruses, particularly those causing Hepatitis B and AIDS, that can be transmitted in the blood of patients. Promulgated after a protracted notice-and-comment rulemaking proceeding, the rule and its supporting reasons occupy 178 densely packed pages in the *Federal Register.* Most employers in the health care industry have accepted the rule, which in essence requires compliance with procedures for health care workers recommended by the Centers for Disease Control (since renamed the Centers for Disease Control and Prevention), the federal agency responsible for the control of contagious diseases. Many of these employers, indeed, had adopted the procedures as soon as the CDC recommended them. Three employer groups, however, challenge the rule—dentists, represented by the American Dental Association, and medical-personnel and home-health employers, both represented by the Home Health Services and Staffing Association. Medical-personnel firms supply health care workers on a temporary basis to hospitals and nursing homes, while home-health firms supply such workers to patients at home.

AIDS is caused by a virus (HIV) that can be transmitted, among other means, by introducing the blood of an infected person into the bloodstream of an uninfected one. If blood of a dental or medical patient who is HIV positive spatters on a health care worker's skin where the skin is cut or abraded, or the worker accidentally sticks himself with a scalpel or hypodermic needle or other medical instrument on which there is fresh blood of an HIV carrier, the worker may become infected—with, so far as anyone knows, invariably fatal results. The AIDS virus is not, however, robust, and is not easily transmitted by the sorts of contact that patients usually have with

health care workers. As of 1991, there had been only 24 confirmed cases of U.S. health care workers infected with the AIDS virus by patients since AIDS was first diagnosed in 1981.

Hepatitis B is a far more common disease than AIDs, though less scary, publicized, or stigmatized. The Hepatitus B virus (HBV) produces antibodies that fight the virus but at the same time destroy liver cells in which the virus has lodged. Although most infected persons recover uneventfully, about 1 percent die and about 6 to 10 percent of adult (and a much higher percentage of child) victims of Hepatitis B become carriers. The virus is much more virulent than the AIDS virus, and the introduction of a carrier's blood into another person's bloodstream is a particularly efficient means of transmission. Unlike the AIDS virus, which cannot survive exposure to air, HBV can survive on the surface of a piece of clothing or other material at room temperature for a week and can thus be spread by dirty laundry. Also unlike the AIDS virus, there is a vaccine against HBV, effective in 85 to 97 percent of healthy adults who receive it. Nonetheless, because of the greater virulence of HBV and the fact that many health care workers are not vaccinated, patient-communicated Hepatitis B kills about 200 health workers in the U.S. per year—roughly 100 times the number of such workers infected by patient-communicated HIV.

The precautions against infection of health care workers by the two viruses is similar, except that the vaccine against HBV offers a protection that has no counterpart with regard to HIV, and contaminated laundry poses a danger of spreading HBV that also has no counterpart with regard to HIV. OSHA's rule reflects the public-health philosophy of "universal precautions," which means precautions against the blood of every patient, not just the blood of patients known or believed likely to be carriers of HBV or HIV. The precautions are various. They include engineering controls (such as requirements for

the location of sinks), work practice controls (such as standards of care in handling contaminated sharp instruments, such as needles), requirements for personal protective equipment such as gloves, masks, goggles, and gowns, requirements for housekeeping (covering such things as the cleaning of contaminated surfaces and laundry and the disposal of contaminated waste), reporting requirements, and provisions for medical care. The rule requires the employer to offer employees who are at risk of exposure to the blood of patients the Hepatitis B vaccine at the employer's own expense, though it allows the employees to decline to be vaccinated. An employee who is involved in an "exposure incident," such as being stuck by a contaminated needle, must be offered at the employer's expense a *confidential* blood test for HBV and HIV; that is, only the employee is entitled to the result of the test.

In deciding to impose this extensive array of restrictions on the practice of medicine, nursing, and dentistry, OSHA did not (indeed is not authorized to) compare the benefits with the costs and impose the restrictions on finding that the former exceeded the latter. Instead it asked whether the restrictions would materially reduce a significant workplace risk to human health without imperiling the existence of, or threatening massive dislocation to, the health care industry. For this is the applicable legal standard. Occupational Safety & Health Act, § 6(b)(5), 29 U.S.C. § 655(b)(5); *Industrial Union Dept., AFL-CIO v. American Petroleum Institute,* 448 U.S. 607, 642-45, 655-56 (1980) (the "benzene" case) (plurality opinion); *American Textile Mfrs. Institute, Inc. v. Donovan,* 452 U.S. 490, 509-12, 530-36 (1981) (the "cotton dust" case). The agency focused on HBV rather than on HIV because of the minute number of health care workers who have been infected by the latter virus. It estimated that the rule would eliminate between 113 and 129 annual deaths of health care workers from Hepatitis B, and a

somewhat higher figure (187 to 197) if deaths of non-workers infected by health-care workers who (but for the rule) would be carriers are factored in as well. (In making this additional calculation, OSHA expressed an uncharacteristic, but as it seems to us commendable, concern with the indirect effects of its rule. On the other hand it did not consider the reduction in medical care that might result from the rule's effect in making the practice of medicine more costly—more on this shortly). Most of these deaths would be avoided by the vaccine, but by no means all, because the vaccine is not a hundred percent effective and, more important, because many health care workers refuse to be vaccinated. Hence the other parts of the rule would have a positive effect even on Hepatitis B; and there is no vaccine (or cure) for AIDS.

OSHA's evaluation of the effects of the rule, relying as it does on the undoubted expertise of the Centers for Disease Control, cannot seriously be faulted, at least by judges. Hence we cannot say that the rule, viewed as a whole, flunks the test of material reduction of a significant risk to workplace health. As for the impact on the health care industry, OSHA estimated the total cost of compliance with the rule at $813 million a year, clearly not enough to break the multi-hundred-billion-dollar health-care industry. The rule's implicit valuation of a life is high—about $4 million—but not so astronomical, certainly by regulatory standards, Cass R. Sunstein, *After the Rights Revolution: Reconceiving the Regulatory State 239* (1990) (App. B), as to call the rationality of the rule seriously into question, especially when we consider that neither Hepatitis B nor AIDS is a disease of old people. These diseases are no respecters of youth; they cut off people in their working years, and thus in their prime, and it is natural to set a high value on the lost years. Nor is death the only consequence of these diseases. AIDS causes protracted pain and disability before death, and Hepatitis B causes pain and disability and often permanent liver damage, even when the patient "recovers."

No doubt the agency's 813 million estimate is an underestimate. It ignores time costs—more precisely, many or most time costs, for the statement accompanying the rule does contain a cost estimate for "work practices." But apparently it is limited to "handwashing/glove change" and to the added time for using "safety syringes." Those are not the only time costs, and the rest seem to have been left out. Individually slight, the time costs of suiting up with protective clothing, and of other preparatory activities required by the rule, could be cummulatively significant. Certain efficiency losses were also excluded, of which we give an example later. But the petitioners made no effort in the rulemaking proceeding to quantify these costs or to provide any basis for supposing them to be huge.

OSHA also exaggerated the number of lives likely to be saved by the rule by ignoring lives likely to be sacrificed by it, since the increased cost of medical care, to the extent passed on to consumers, will reduce the demand for medical care, and some people may lose their lives as a result. The agency's consideration of the indirect costs of the rule is thus incomplete. Cf. *Competitive Enterprise Institute v. NHTSA*, 956 F.2d 321 (D.C. Cir. 1992); *International Union, UAW v. OSHA*, 938 F.2d 1310, 1320 (D.C. Cir. 1991). How many lives the rule is likely to sacrifice, however, we do not know; and again the petitioners make no effort to come up with a number. So while $4 million doubtless underestimates the agency's implicit valuation of each life actually likely to be saved by the rule, we do not know how great the underestimate is and we cannot resolve our doubts against the agency. We add that the $4 million ignores the benefits to workers who will be spared illness—for remember that 99 times as many people get Hepatitis B as die from it.

As an original matter we might have been inclined to think that the regulation of the safety of the medical and dental workplace could be left largely to the market, that

doctors, dentists, and other health care workers have a stronger incentive than the government to protect themselves from health hazards at reasonable cost, that their employees are compensated in their wages for what is after all a modest risk, and that health care workers who refuse to be vaccinated against Hepatitis B are knowingly assuming the risk and should be left to bear the consequences without government interference. But the occupational safety and health law is constructed on different premises that we are not free to question, and perhaps the infectious character of HIV and HBV warrant even on narrowly economic grounds more regulation than would be necessary in the case of a noncommunicable disease.

The petitioners, moreover, do not attempt to blast the entire rule out of the water. They do not argue that its net contribution to the safety of health workers is likely to be trivial, or its net costs crushing. They do not contend that there should be no regulation of bloodborne pathogens. They zero in on the particular features of the rule that pinch their clienteles and argue that the pinch is so tight that we should invalidate the rule insofar as it applies to the industries that they represent. We start with the dentists. Mainly they object that they have been lumped in with medical personnel, such as surgeons, who are far more exposed to patients' blood than dental workers are and, in other respects as well, work under relevantly different conditions. For example, although the rule is entitled a rule about *blood*borne pathogens, it requires universal precautions in any dental procedure in which the patient's saliva may drip or spray or splatter on the dental worker. But it is not quite true that OSHA treated all branches of the health care industry in a lump. It gave separate consideration to every point raised before it by the dental association. It pointed out that the saliva of dental patients frequently contains blood—even in such routine procedures as having one's teeth cleaned by a dental hygienist—and that it is possible, though far

from certain, that even a small quantity of blood, diluted by saliva or some other fluid, can sometimes be infective. This was not some fantasy of OSHA. The Centers for Disease Control, while generally exempting saliva from the list of body fluids to which universal precautions should apply, recommended "special precautions" for dental workers exposed to saliva from patients. Did the CDC mean universal precautions? Its language is unclear, requiring interpretation. OSHA was entitled to adopt an interpretation that leaned "on the side of overprotection rather than underprotection." *Industrial Union Dept., AFL-CIO v. American Petroleum Institute, supra,* 448 U.S. at 656.

What OSHA did not do was attempt to disaggregate the risk industry by industry. While it carefully disaggregated the costs of compliance, to see whether any industry within the health care sector would be imperiled by the rule, it did not attempt to determine separately the risk of HIV or HBV infection in dentistry, in home-health services, in thoracic surgery, in ophthalmology, and so forth. It did not attempt to determine the number of dental employees, say, who have contracted Hepatitis B from their patients; and it inflated the fact that only 1 of the 24 health care workers infected by a patient with AIDS in the U.S. was a dental employee by calling it a "signicant percentage" of all occupational HIV infections. Well, 4.16 percent is a significant percentage, but not a meaningful one in this case, given the smallness of the sample. Citing cases like *International Union, UAW v. OSHA*, 938 F.2d at 1322, the dental association argues that the finding that the benzene opinion requires OSHA to make—"that the workplaces in question are not safe." 448 U.S. at 642—entails a determination of the safety (or riskiness) of, at the least, each *type* of workplace.

OSHA cannot impose onerous requirements on an industry that does not pose substantial hazards to the safety or health of its workers merely because the industry is a part of some larger sector or grouping and the agency

has decided to regulate at wholesale. That would be an irrational way to proceed. But neither is the agency required to proceed workplace by workplace, which in the case of bloodborne pathogens would require it to promulgate hundreds of thousands of separate rules. It is not our business to pick the happy medium between these extremes. It is OSHA's business. If it provides a rational explanation for its choice, we are bound. *Associated Builders & Contractors, Inc. v. Brock*, 862 F.2d 63, 68 (3d Cir. 1988). It explained that while the cost of compliance with the precautions that the CDC has recommended (and OSHA has required) against bloodborne pathogens varies in a readily determinable fashion from industry to industry, the risk of infection does not. The risk goes with practices (so protective clothing is required only where being splashed with blood or other infective liquid can reasonably be anticipated, whether it is a dentist's office or a hospital operating room) rather than with industries, and the rule is therefore based on practices rather than on industries. The HIV or HBV carrier bears menace with him as he makes the rounds from health care provider to health care provider. The risk of blood splatters and needlesticks is greater in some medical procedures than in others, but a dental hygienist is as likely to be splattered by blood contained in saliva as is many a worker in a hospital or a doctor's office. The idea behind requiring universal precautions for health care workers is to protect those workers in any situation in which there is a nontrivial risk of physical contact with a patient's blood, and these situations arise in dentists' offices as well as in doctors' offices and hospitals. OSHA was required neither to quantify the risk to workers' health nor to establish the existence of significant risk to a scientific certainty. *Industrial Union Dept., AFL-CIO v. American Petroleum Institute, supra*, 448 U.S. at 655-56. It is true that because fewer people have dental than medical insurance, and therefore more people pay for dental care out of their own pockets, the higher price of dentistry that

is a likely consequence of the rule will have a greater impact on demand; and inadequate dental care is a source of pain and suffering. But again the dental association made no effort to quantify this impact, though techniques for doing so exist in economics.

As to the specific precautions required by the rule, the association makes a number of arguments, of which a representative example is that children may be traumatized by the sight of a dentist wearing goggles. "Traumatized" is putting it too strongly, and the rule does not require goggles—at least for most dental procedures, ordinary glasses with side shields are all that is required. Nonetheless the problem of calming children in the dentists's chair, without resort to nitrous oxide, is a serious one that the rule may aggravate, but again the dental association makes no effort to estimate the gravity of the harm. And while as we have suggested there is a time cost to decking oneself out in protective clothing which OSHA ignored, so does the dental association. In this example, and others unnecessary to discuss, the assocation is contesting requirements that, whether wise or not, are within the broad bounds of the reasonable, involving as they do technical issues on which the judgments of the CDC and OSHA are entitled to respect by the nonspecialist, biomedically unsophisticated Article III judiciary, at least in the absence of a more systematic showing of harms than attempted by the dental association.

This is true even with regard to the question whether a health worker should be permitted to conceal his awareness of being infected from his employer and the employer's patients. The problem with nonconfidential medical tests is that the cost of flunking is high—loss of a job, for example—and this deters people from taking the test. A dental worker who knew that if he were infected he would lose his job might simply not report an exposure incident. The dental association does not argue that testing should not be encouraged, or alternatively that all

dental workers should be tested regularly without regard to any exposure incidents. It asks us to balance the pros and cons of the confidentiality provision. That is not our job. We add that nothing in the rule forbids a dentist to require his employees to have a periodic HIV or HBV test, with disclosure of the results to him. The rule's provision on confidentiality is limited to the test that an employer is required to offer a worker after an exposure incident.

The dental association complains that the rule goes too far in requiring dentists to "ensure" that their employees comply with the requirements of the rule. They say this imposes strict liability, which OSHA acknowledges it cannot do. *Brennan v. OSHRC*, 502 F.2d 946, 951 (3d Cir. 1974); *Brennan v. Butler Lime & Cement Co.*, 520 F.2d 1011, 1017 (7th Cir. 1975); *Pennsylvania Power & Light Co. v. OSHRC*, 737 F.2d 350, 354 (3d Cir. 1984). In so saying they may seem not really to be challenging the rule but rather to be raising an interpretive question—how strictly will OSHA interpret "ensure"? Interpretive questions that cannot be answered until a rule is applied are premature when raised in a challenge to the rule on its face, mounted at the time the rule is promulgated. But here the question is neither unanswerable, nor severable from questions that clearly are ripe, such as whether the costs of compliance with the rule will be so staggering as to imperil the dental industry (in which even the rule would be invalid). The stricter the liability, the more costly the rule. It is reasonably plain, however, that OSHA did not by using the word "ensure" seek to impose strict liability. It explained that the employer's responsibility doesn't end with furnishing his employees with protective gear, for example: he must do everything he can reasonably be expected to do to see that they use it. Like an employer made liable for his employees' conduct not by the principle of respondeat superior (strict liability) but by the negligence principle. *Lancaster v. Norfolk & Western Ry.*, 773 F.2d 807, 818-19 (7th Cir. 1985), which re-

quires due care in hiring, training, supervising, monitoring, disciplining, and retaining employees—the kind of employer liability imposed in sexual harassment cases. *Guess v. Bethlehem Steel Corp.*, 913 F.2d 463, 465 (7th Cir. 1990), in other civil rights cases, *Hunter v. Allis-Chalmers Corp.*, 797 F.2d 1417, 1421-22 (7th Cir. 1986), and in cases under the common law's "fellow servant" doctrine, *Pomer v. Schoolman*, 875 F.2d 1262, 1266 (7th Cir. 1989)—the employer subject to OSHA's rule on bloodborne pathogens must take all reasonable measures to prevent his employees from violating the rule, but if despite these measures the employee violates the rule, the employer is off the hook. *Pennsylvania Power & Light Co. v. OSHRC*, *supra*; *Capital Electric Line Builders of Kansas, Inc. v. Marshall*, 678 F.2d 128 (10th Cir. 1982); *Brock v. L.E. Myers Co.*, 818 F.2d 1270, 1277 (6th Cir. 1987).

The costs of compliance with OSHA's rule, once the issue of strict liability for unforeseeable misconduct by employees is laid to one side, can hardly be thought so great as to imperil dentistry. Annualized, these costs are estimated to be equal to less than one-third of one percent of the industry's annual revenues. This may overstate the actual cost, not to society as a whole (*International Union, UAW v. OSHA*, *supra*, 938 F.2d at 1320) but to the industry. When an industry is subjected to a higher cost, it does not simply swallow it; it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers (granted, those suppliers may include the firms constituting the industry). This very point is the basis of the dental association's argument that OSHA's rule is likely to cause a deterioration in dental care as dental patients flee the higher prices resulting from the industry's efforts to shift some of the costs of compliance with the rule to its customers. There are some omitted costs, as we have noted, but not enough to make a decisive difference; nor does the association emphasize them.

The dental association makes some other jabs at the rule, but they have less merit than those we have discussed so we move on to the objections of the home health and medical personnel industries. These objections have greater force because they are based primarily on the fact, which has no counterpart in dentistry or for that matter in most other branches of the health industry, that the home health and medical personnel industries—we'll call them the health personnel industry for short—do not control the sites at which their employees work. This does not affect compliance with the parts of the rule relating to HBV vaccination, post-exposure testing and treatment, and recordkeeping, but it does affect the ability of the employer to comply with the requirements for protective clothing and equipment, because his employees do not work in his presence. It especially affects the employer's ability to comply with site-specific precautions required by the rule, such as ensuring that the work site is maintained in a clean and sanitary condition and that the worker has convenient access to running water in the event of exposure to blood or other potentially infective materials. These problems do not seem serious with regard to the branch of the industry that supplies medical personnel to hospitals, nursing homes, and other facilities that are themselves required to comply with the rule, but they could be serious with regard to the branch of the industry that supplies personnel to homes. Save for allowing the employer to substitute handwashing chemicals for a ready source of running water, the rule gives no recognition to the special problems of the industry although they were brought to OSHA's attention during the rulemaking proceeding. OSHA's brief relies on what it calls the "multi-employer worksite defense," whereby an employer that cannot control a hazard is not liable for the exposure of its employees to the hazard if it took whatever precautionary steps were reasonable in the circumstances (or reasonably lacked the knowledge to recognize a condition

as hazardous, but that is not a factor here). In effect OSHA asks us to read the defense into the rule.

Is the absence from the rule of any explicit recognition of the acute compliance problem apparently faced by the health personnel industry, and in particular the branch that supplies medical workers to patients' homes, a fatal omission? Administrative rules and decisions, like statutes, are enacted against a background of existing laws and understandings that do not have to be repeated in every new rule in order to have force. Perhaps the multi-employer worksite defense is so well established in the law of occupational safety and health that it formed part of the implicit background of the bloodborne-pathogens rule, which would explain OSHA's seeming insouciance in assimilating the home personnel industry to health care industries that control the sites at which the care is provided. Apart from its having been clearly stated by the Occupational Safety and Health Review Commission, which reviews orders of OSHA citing employers for violations of the Occupational Safety and Health Act, and endorsed by every court to consider it, see, e.g., *Anning-Johnson Co.*, 4 O.S.H.C. 1193, 1198-99 (1976); *Harvey Workover, Inc.*, 7 O.S.H.C. 1687, 1689 (1976); *D. Harris Masonry Contracting, Inc. v. Dole*, 876 F.2d 343 (3d Cir. 1989); see also *Anning-Johnson Co. v. OSHRC*, 516 F.2d 1081, 1089 (7th Cir. 1975), the rule or some variant of it is implicit in the principle we have just examined that the Act does not impose strict lability.

One problem, however, is that the Review Commission is not OSHA. OSHA is legislator and prosecutor, OSHRC the judge. *Martin v. OSHRC*, 111 S. Ct. 1171, 1174 (1991); see also *Cuyahoga Valley Ry. v. United Transportation Union*, 474 U.S. 3, 7 (1985) (per curiam). By failing to mention the multi-employer worksite defense in the bloodborne-pathogens rule, OSHA may, despite its appellate lawyers' disclaimer—which the doctrine of *SEC v. Chenery Corp.*, 318 U.S. 80 (1943), obliges

us to ignore—be signifying its disagreement that the defense is part of the law. If so, this could mean that OSHA was planning to enforce the rule as written, that is without any such defense. If that is the proper interpretation of the rule's silence, we would have to invalidate the rule (in part), as we think the defense *is* part of the law. The alternative interpretation of the rule's silence is that OSHA accepts the defense as something that is to be read into all of its rules: that OSHA has bowed to the Review Commission and the courts.

We need not choose between these interpretations. Silence as acquiescence would not be an adequate response by OSHA to the circumstances of this case. The multi-employer worksite defense was developed for the construction industry and has, so far as we are able to discover, rarely been applied outside of it. What contours it should have in so unusual a worksite setting as the health personnel industry presents should not be left to appellate tribunals, whether OSHRC or this court, to decide. OSHA should set the contours in the first instance. Maybe they should be narrower in this industry than in the construction industry, maybe broader, maybe different. So important a question should be settled now, not left to enforcement proceedings. Since we know that the Occupational Safety and Health Act does not impose strict liability on employers, we know that the members of the health personnel industry need make only reasonable efforts to comply with the rule; but what this means at sites that the employers do not control eludes us. Can the employer take the position that he has no responsibility for the condition of those sites? Or must he inspect each site before he allows his employees to work there? Must he do that even if the site is a private home? Who knows? OSHA had an obligation to consider such questions and the general issue that they present before imposing a medley of restrictions that, so far as appears, the industry cannot comply with.

So the rule must be vacated insofar as it applies to sites not controlled either by the employer or by a hospital, nursing home, or other entity that is itself subject to the bloodborne-pathogens rule. The other objections lodged by the health personnel industry against the rule, however, either duplicate those of the dental association or plainly lack merit. So in the main the rule must be upheld. Which is not to say that it is a good rule. It may be unnecessary; it may go too far; its costs may exceed its benefits. Concern with the cost of health care in the United States is growing, and OSHA has received a steady drumbeat of criticisms even from supporters of public regulation of occupational health and safety. E.g., Sunstein, *supra* (index references to Occupational Safety and Health Act and Occupational Safety and Health Administration). But our duty as a reviewing court of generalist judges is merely to patrol the boundary of reasonableness, and, with the exception we have noted, OSHA's bloodborne-pathogens rule—accepted as it has been by most health care industries and based as it is on the recommendations of the nation's, perhaps the world's, leading repository of knowledge about the control of infectious diseases—does not cross it.

The petition to review filed by the American Dental Association is denied. The petition of the Home Health Services and Staffing Association is granted in part and denied in part, as explained above.

COFFEY, *Circuit Judge,* concurring in part, dissenting in part. Section 3(8) of the Occupational Safety and Health Act defines "occupational safety and health standard" as a standard which requires the adoption of practices *"reasonably necessary or appropriate* to provide safe or healthful employment and places of employment." 29 U.S.C. § 652(8) (emphasis added). Section 6(b)(5) of the Occupational Safety and Health Act states:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under

> this subsection, shall set the standard which most adequately assures, *to the extent feasible, on the basis of the best available evidence,* that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."

29 U.S.C. § 655(b)(5) (emphasis added).

The dental profession, and the employees in the home health care and temporary medical services fields, argue convincingly that it is improper for the Occupational Safety and Health Administration's final bloodborne pathogens standard to be applied uniformly to their respective fields since the levels of exposure to bloodborne pathogens are vastly different among the various disciplines. The rule adopted can best be classified as an attempt to try to kill a fly with a sledgehammer. The rule was drafted partially in response to the public hysteria surrounding AIDS created by the media's failure to balance their reporting with scientific data on transmission. The rule was not drafted in response to an established significant risk of harm to employees. The dangers of transmitting the bloodborne pathogen hepatitis B have been well-established for years yet for reasons unexplained OSHA did not concern itself with that risk in the workplace prior to November 1987. Based on the record, I am forced to assume that because of the excessive media coverage regarding the AIDS virus, fueled by one single episode involving Kimberly Bergalis in Florida contracting AIDS from her dentist,[1] OSHA decided to promulgate this overexpansive rule (combining the AIDS virus with hepatitis

[1] Medical experts have to date been unable to scientifically determine how the dentists, David Acer, infected his five patients. It has been reported that he may have intentionally infected them. Unfortunately, if it was in fact a criminal act, no amount of precaution could have prevented it. *See, e.g., AIDS Infection Charge,* Wash. Post, June 11, 1992 at A12.

B) in the health care field.[2] The rule unduly burdens health care employers, including but not limited to dentists, doctors and hospitals, while offering but minimal benefit to their employees, and furthermore it is estimated that it will increase health care costs some $817 million annually. Additionally, the rule duplicates the scientifically based and well-reasoned guidelines of the Centers for Disease Control and Prevention (CDC) a governmental agency medically and scientifically qualified to determine and evaluate if there is in fact a significant risk in the health care area and, if so, propose reasonable, efficient guidelines.

The petitioners (American Dental Association and Home Health Services and Staffing Association) base their challenges on four theories: 1) OSHA failed to establish a significant risk within their individual respective disciplines, and thus, no basis exists for OSHA to regulate; 2) OSHA has failed to establish that the final rule will result in substantial benefit to health care workers, much less that the guidelines and regulations of the CDC and the respective states are inadequate; 3) the rule is aimed at protecting employees only and thus lacks concern for and fails to protect the consumer (dental patients and home health care patients) by increasing health care costs and at the same time denying the consumer access to essential information necesssary to the granting of informed consent; and 4) there are flaws in the feasibility analysis. I concur with the majority holding concerning the failure of the rule to make an exception for employers who have no control over the work site (home health

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[2] The rule making process actually began with a petition in 1986 from the American Federation of State, County and Municipal Employees requesting OSHA to reduce the risk to employees from infectious agents. 56 Fed. Reg. 64006 (1991). Soon thereafter, other unions (Service Employees International Union, National Union of Hospital and Healthcare Employees, RWDSU Local 1199 —Drug, Hospital and Healthcare Union) also requested a rule. *Id.*

and temporary medical services) slip op. at 15. I suggest that the United States Congress must address the question of whether there is a need to duplicate the education, investigation and prevention efforts of the CDC and state health agencies, thus increasing health care costs, and whether OSHA is the proper agency to regulate health care given their lack of experience, knowledge and expertise in comparison to the CDC and state health agencies. In the alternative, the entire rule should be remanded to OSHA for the reasons detailed in this opinion.

I. *SIGNIFICANT RISK*

In *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 642-44, 100 S. Ct. 2844, 2864-65 (1980) (the *Benzene* case), the Supreme Court required that OSHA determine whether a "significant risk" exists before it can promulgate a rule. The Court's mandating this analysis demonstrated concern that an insignificant risk must not be allowed to "justify pervasive regulation limited only by the constraint of feasibility" and to restrain OSHA's "power to impose enormous costs that might produce little, if any, discernible benefit." *Benzene*, 448 U.S. at 645, 100 S. Ct. at 2865. For regulations under § 6(b)(5), such as the bloodborne pathogens standard, "the logic of *Benzene* thus calls for a fairly high standard of significance." *International Union, UAW v. OSHA*, 938 F.2d 1310, 1322 (D.C. Cir. 1991). The *Benzene* case places the burden of proof on OSHA to demonstrate that a significant risk of harm to employees exists. *Benzene*, 448 U.S. at 653, 100 S. Ct. at 2869.

Additionally, § 6(b)(5) of the Occupational Safety and Health Act mandates that OSHA standards satisfy the "best available evidence" and feasibility requirements. 29 U.S.C. § 655(b)(5). OSHA states that in an attempt to satisfy the best available evidence requirement concerning the risk of bloodborne pathogens it conducted a number of hearings and received a myriad of comments prior

to the adoption of the final rule.[3] Further, OSHA sets forth that it reviewed nationwide statistical sample surveys from health care disciplines [4] to determine the possibility of exposure to blood or other potentially infectious materials in twenty-four (24) industry sectors.[5] 56 Fed. Reg. 64041-64043.

Even though the U.S. Supreme Court held in *American Textile Mfrs. Institute, Inc. v. Donovan,* 452 U.S. 490, 101 S. Ct. 2478 (1981) (the *Cotton Dust* case), that OSHA is not required to conduct a cost benefit analysis when promulgating a rule under § 6(b)(5), the Supreme Court explained the propriety of OSHA adopting the most cost-effective regulation:

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[3] OSHA states that during its regional hearings, it analyzed the testimony and information of some 400 witnesses plus 3000 written comments, 56 Fed. Reg. 64008. For reasons unexplained, OSHA decided to address the entire health care industry (combining disciplines with hundreds of thousands of individuals in diverse and unrelated fields as well as joining together both rural and metropolitan areas, *see infra* note 5) rather than addressing the risk of exposure to bloodborne pathogens in their unique and respective disciplines. As a result, the cumbersome 174 page rationale for the rule in the *Federal Register* can be digested and analyzed with only the greatest of difficulty.

[4] The sectors of health care workers OSHA investigated include physicians and surgeons, registered nurses, therapists, lab technicians, emergency medical technicians, surgical technicians, other health professionals, licensed practical nurses, therapy assistants, physician assistants, medical assistance, nursing aides, dentists, dental hygenists, and dental assistants.

[5] The 24 industry sectors include: offices of physicians (including ambulatory medical services), dental offices, hospitals, medical and dental laboratories, nursing homes, residential care facilities, dialysis centers, drug treatment centers, home health care, hospices, government outpatient facilities, blood collections and processing, health clinics and industrial facilities, personnel services, funeral homes and crematories, research laboratories, linen services, medical and dental equipment repair, law enforcement, fire and rescue, correctional institutions, schools, lifesaving, and regulated waste removal. 56 Fed. Reg. 64041.

> "In addition, if [1] the use of one respirator would achieve the same reduction in health risk as the use of five, [2] the use of five respirators was 'technologically and economically feasible,' and [3] OSHA thus insisted on the use of five, then the 'reasonably necessary or appropriate' limitation might come into play as an additional restriction on OSHA to choose the one-respirator standard. In this case we need not decide all the applications that § 3(8) might have, either alone or together with § 6(b)(5)."

452 U.S. at 514 n.32, 101 S. Ct. at 2493 n.32. Thus it is reasonable to expect OSHA not only establish that a significant risk exists but also that the regulation adopted is the most cost-effective procedure.

While I agree with the majority that "we are not free to question" Congress' intentions in granting OSHA the power to regulate the workplace, maj. op. at 6, I do not believe that Congress ever intended that OSHA regulate the highly technical health care field. Congress was in no position in the year 1970 to foresee the dramatic advancements in the field of medical technology, such as heart catheterization and angioplasty procedures, heart bypass surgery, organ transplants, microscopic surgery, and the developments in nuclear medicine among others. Nor do I think Congress intended for OSHA to invade the privileged relationship between medical professionals and their patients. Accordingly, Congress may wish to revisit this matter to determine whether OSHA is the most qualified agency to regulate health care as we move into the 21st century.

II. *DISAGGREGATING INDUSTRIES WHEN PERFORMING SIGNIFICANT RISK ANALYSIS*

The majority acknowledges that "OSHA cannot impose onerous requirements on an industry that does not pose substantial hazards to the safety or health of its workers

merely because the industry is a part of some larger sector or grouping and the agency has decided to regulate at wholesale." Maj. op. at 8. In order to achieve its desired result of regulation, OSHA made a hodgepodge of findings (estimating the number of health care workers infected with hepatitis B, and combining the risk of exposure to all bloodborne phathogens in the various fields of medical and dental endeavor) resulting in nothing but a generalized determination of significant risk applicable to the twenty-four industry sectors noted above. It would have been more scientifically acceptable had OSHA disaggregated the twenty-four sectors (even those with as few as 8,000 employees, *see infra* note 8) to determine if in fact a scientifically established risk existed in a specific field of health services as opposed to a hypothesized risk.[6] Although I realize OSHA need not "establish the existence

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[6] OSHA also considered those non-healthcare workers who might incur occupational exposure to blood (including janitorial, laundry and school workers) to have risk similar to health care professionals. "Therefore OSHA will use the data available for health care workers with occupational exposure to predict the HBV infection risk to any worker with occupational exposure to blood or other potentially infectious material." 56 Fed. Reg. 64026. OSHA combined the non-healthcare worker with the trained professional health care worker but disregarded the fact that the non-healthcare worker may not have had any training in infection prevention as contrasted with medical and dental professionals who have had training during their respective scholastic endeavors plus followup seminars. Interestingly, in an area where I agree OSHA might well have the required expertise, the rule does not govern barbers and cosmetologists, where cleanliness should be mandated but is not always the rule. Barbers and cosmetologists when using sharp instruments (including razors and scissors) are exposed to their clients' blood as well as exposing clients to their own blood, more frequently than many other disciplines governed by this rule. The frequency of a barber or tonsorial employee inadvertently drawing blood from a customer warrants greater consideration of the likelihood of spreading infectious viruses like HBV and HIV than does a professional in a one-chair dental office in a rural community, an orthodonist, or one who practices in a specialty where laceration or puncturing of the gum tissue is the exception.

of significant risk to a scientific certainty," maj. op. at 9, OSHA must do more than rely on estimates of risk. OSHA's application of the law in that manner is directly contrary to the D.C. Circuit's recent decision in *International Union, UAW v. OSHA*, which states:

> "OSHA nowhere explains its logic. Just because paper mill equipment (which was already subject to a lockout requirement) poses a significant hazard does not mean that sewing machines do. While we have recognized OSHA's need to avoid "minuscule industry subcategories" for administrative convenience, . . . *there are no obvious barriers to disaggregation here. In fact, OSHA has in past years promulgated a wide variety of industry and equipment-specific lockout standards.* As we have insisted that OSHA explain its refusal to disaggregate at the behest of unions claiming that reliance on broad categories denied them adequate protection, . . . we similarly remand for it to explain how its aggregated approach here conforms to its interpretation of the act."

938 F.2d at 1322 (emphasis added) (citations omitted).

Certainly OSHA can neither logically nor reasonably claim that the dental, home health and temporary medical personnel sectors are "minuscule industr[y] subcategories" when one considers that there are some 316,000 affected dental employees, 212,246 affected home health employees and 163,477 affected temporary medical personnel 56 Fed. Reg. 64055. An example of OSHA's hodgepodge of findings is the method it used in determining whether a significant risk of infection exists. OSHA combined the risk of infection during surgical procedures in large metropolitan area public hospitals with the risk in a single chair dental practice and in a home health care environment (private residence care). As established in this opinion, OSHA has failed in the record to accurately or scientific-

ally analyze the risk of exposure to bloodborne pathogens. This is most evident from OSHA's decision to combine the risks of the individual sectors in the health care area and then conclude that its self-generated, artificial risk level exists in each respective health care area. It is interesting to note that this commingling of diverse groups is contrary to OSHA's prior practice of disaggregating industries in rule making proceedings for purposes of analyzing significant risk when promulgating a rule governing exposure to toxic substances. *See* 29 C.F.R. at 1910.1043 (a)(2) (OSHA's final *Cotton Dust* standard); *Texas Independent Ginners Ass'n v. Marshall,* 630 F.2d 398, 403 (5th Cir. 1980).[7] OSHA properly excluded the cotton ginning industry from the airborne concentration of cotton dust standard because "gin employees are only exposed to cotton dust for a short season, . . . the proper maximum level is not known for such seasonal exposure and . . . the emission controls are infeasible . . . ." *Id.* at 403.[8] The court added that imposing emission controls on the cotton

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[7] There are other examples of OSHA excluding specific sectors from a rule. *See* 29 C.F.R. §§ 1910.1001(a)(1)-(2), 1910.1025(a)(2) (asbestos, tremolite, anthroyphyllite, actinolite, and lead exposure rules); 29 C.F.R. § 1910.1018(a) (inorganic arsenic exposure rule); 29 C.F.R. § 1910.261(a)(1) (pulp, paper, and paperboard mill regulation).

[8] The ginners numbered at most 58,968 employees (calculation based on 21 employees for each of 2808 cotton gins in the U.S., this number is probably quite high since many ginners work at more than one gin during the season). 43 Fed. Reg. 27427 (1978). The total number of employees affected by cotton dust was somewhere between 420,000 and 800,000. *American Textile Mfrs. Institute Inc. v. Donovan,* 452 U.S. 490, 500, 101 S. Ct. 2478, 2485 (1981); *AFL-CIO v. Marshall,* 617 F.2d 636, 646 (D.C. Cir. 1979).

Another example of OSHA drafting rules for a particular segment of industry is the promulgation of rules to cover only those 8,136 employees in the underground construction industry, 54 Fed. Reg. 23824, 23846 (1989), 67,728 employees affected by ethylene oxide, 53 Fed. Reg. 11,414, 11.421 (1988), 69,000 (OSHA estimate) loggers, 54 Fed. Reg. 18,798, 18,810 (1989), and 145-180.000 shipyard employees, 53 Fed. Reg. 48,150, 48,162 (1988).

ginning industry would "increase the construction cost of the average gin by sixty-five percent and would increase the farmer's cost by fifty percent." *Id.* Certainly, if OSHA is able to create an industry-specific feasibility analysis for the cotton ginning industry of 58,000 employees and other industries (*see supra* footnote 8), it can and should in fairness to the dental profession, consisting of over 316,000 employees, be required to create an individual industry specific significant risk analysis. 56 Fed. Reg. 64055.[9] Apparently OSHA realized it was unable to establish a significant risk in the appellants' respective fields and/or for the sake of convenience chose to combine the risk present in the entire health care area.

Furthermore, based on the record it is evident that OSHA failed to consider the unique, separate and distinct risks of occupational exposure to the HBV and HIV viruses when it determined that there is a "significant risk" in the health care profession. For instance, *of the twenty-five cases studied of health care workers infected with HIV through occupational exposure not one home health care employee and only one dentist (of the 100,000 practicing dentists in the United States) tested positive.*[10] 56 Fed. Reg. 64017-19 (listing the cases worldwide where occupational exposure to HIV infected blood was the suspected cause of a healh care worker's positive HIV test). Certainly *one suspected* case of occupational *transmission of* HIV falls far short of establishing *a significant risk* to the dental field of over 100,000 practicing dentists and thus fails to warrant much less justify OSHA's all-protective and all-encompassing rule.

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[9] 313,219 of those employees are dentists, dental hygienists or dental assistants who have received training in infectious disease control. The remainder are housekeepers or provide janitorial services in dental offices. *See* 56 Fed. Reg. 64043.

[10] The dentist denied having other risk factors for AIDS (such as intravenous drug use) but OSHA stated "other modes of transmission cannot be ruled out." 56 Fed. Reg. 64017, 64019.

OSHA, in its questionable quantitative risk assessment, perhaps in an attempt to enlarge its sphere of influence or as a result of responding to well-organized political pressure, failed to analyze and weigh the varying risk levels among respective disciplines (dentists, home health, surgeons, etc.) when determining significant risks for HBV infection due to the lack of epidemiological data relating to the individual disciplines. 56 Fed. Reg. at 64023-64032. To fill this void, OSHA chose to rely on those CDC statistics that it deemed helpful in determining the annual and lifetime risk levels for HBV infection in the health care field as a whole. *Id.* at 64026 ("Of the 280,000 HBV infections each year (based on 1988 Hepatitis Surveillance data), CDC estimates that 8,700 cases occur in health care workers with occupational exposure . . . ."). OSHA's use of the HBV statistics is highly suspect in that they merely relied on an estimate of the number of infected health care employees rather than determining the number through a scientific survey. Without the use of these speculative statistics, OSHA would in all probability have been unable to establish compelling results to satisfy the significant risk requirement in either the dental or the home health disciplines.

OSHA's decision to ignore varying risk levels in the respective health care disciplines appears to be nothing but a scheme to achieve a desired result for the sake of "administrative convenience." *See International Union*, 938 F.2d at 1322. The failure to analyze, quantify, and document the data on the particular risk factors the dental, home health, and temporary medical services individually might incur vis-à-vis the other identified health care sectors results in a quagmire of highly suspect estimates of the risk of HBV infection in the appellants' disciplines. OSHA, as have others before, demonstrated the truth of the well-known saying that people can use statistics to make any point they want. Above all, this type of "reliance on overbroad categories denie[s] [industries] adequate protection" from overreaching regulation. *See id.*

OSHA conceded the effect of *International Union* when it stated, "[that case] stands only for the proposition that OSHA must consider any record evidence that shows a wide variation in incident rates among industries in deciding whether to regulate on an aggregated basis." OSHA Brief at 17. Because of the established "wide variation in incident rates" of exposure to bloodborne pathogens, OSHA, if it was in fact attempting to achieve accuracy, should have disaggregated the individual disciplines in determining the existence of a significant risk.

The professional training the vast majority of health care workers undergo in infectious disease prevention, in addition to complying with the CDC Guidelines, and the respective state and professional regulations are more than an adequate safeguard to combat the minimal risk of infection existing in a dental office or home health care place of employment. On October 28, 1991, Congress enacted a law requiring that states adopt and enforce the 1991 CDC guidelines. *See* Pub. L. No. 102-141, 105 Stat. 876, § 633 (1991). Because of the Supreme Court's ruling in *Gade v. National Solid Wastes Management Ass'n*, 112 S. Ct. 2374 (1992), the OSHA regulations preempt any comparable state regulations, i.e., the 1991 CDC guidelines. Interestingly, the CDC guidelines *are patient oriented as contrasted with the OSHA rule which is employee oriented.*

The OSHA rule leaves much question in light of the fact that the dentists and their support staff are well-trained during their respective dental educational programs as well as their continuing professional dental seminars in how to prevent and control exposure to infection but at the same time the consumer-patient is not as fortunate and ih thus uninformed as to both the risk and the techniques or methods of prevention. Rather than having the CDC and OSHA rules conflict with one another, resulting in confusion as well as government waste from duplication of effort, one governmental organization should be drafting and be responsible for enforcing a

logical, scientifically acceptable, cost-conscious rule which would in turn protect not only the medical and dental personnel but the consumer-patient as well.

I understand that OSHA did consider some of the Dental Association's concerns, *see, e.g.*, 56 Fed. Reg. at 64103 (addressing the ADA's argument that saliva should not be included in the standard), but in large part this *pro forma* treatment of challenges to the standard was inadequate. OSHA did not specifically find that dentists and home health workers were exposed to risk anywhere near a level that could be labeled significant.

III. *SIGNIFICANT BENEFITS*

Benzene states "that Congress intended, at a bare minimum, that [OSHA] find a significant risk of harm and therefore a probability of significant benefits before establishing a new standard" and requires that the Occupational Safety and Health Administration find that "a place of employment is unsafe-in the sense that significant risks are present and can be eliminated or lessened by a change in practices." *Benzene*, 448 U.S. at 642, 645, 100 S. Ct. at 2864-65.[11] The starting point for this significant risk

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[11] Section 2 of Executive Order No. 12,291 provides:

> In promulgating new regulations . . . all agencies, to the extent permitted by law, shall adhered to the following requirements . . .
>
> (b) Regulatory action shall not be undertaken unless the potential benefits to society from the regulation outweigh the potential costs to society;
>
> (c) Regulatory objectives shall be chosen to maximize the net benefits to society . . . .

46 Fed. Reg. 13,193 (1981). In *Corrosion Proof Fittings v. E.P.A.*, 947 F.2d 1201 (5th Cir. 1991), the court emphasized the need for the Environmental Protection Agency to exercise reasonable judgment when regulating toxic substances and to weigh the burden of a proposed regulation with the benefit. *Id.* at 1220-23. I realize OSHA and EPA operate under different enabling statutes, but the holding of *Corrosion Proof Fittings* offers guidance as to how all federal agencies should regulate.

analysis should be the current state of regulation and the risks present thereunder based on recognized and accepted empirical data. OSHA admittedly did not consider the present state of regulation including the CDC Guidelines adopted by the states,[12] other individual state and professional regulations, and the increased use of HBV vaccinations in the dental profession (71% of the nation's roughly 100,000 dentists are vaccinated, while 41% of the nearly 5 million health care workers in the entire health care profession are vaccinated, 56 Fed. Reg. 64027, 64092). OSHA Brief at 20. OSHA acknowledges that the HBV vaccination is 96 percent effective, *id.* at 64027, and "[t]he risk of HBV infection is most efficiently and dramatically reduced by vaccinating all workers exposed to blood and other potentially infectious materials." *Id.* at 64036. Therefore, mandating HBV vaccination for all health care personnel insures far greater reduction of risk at a minimum of expense than do the requirements of wearing shoe covers or thirty-year record keeping, etc. I certainly do not oppose the reasonable recognized safeguards including but not limited to the use of goggles, gloves, masks, sterilization and waste disposal in a hospital

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[12] On July 12, 1991, the Center for Disease Control (CDC) issued recommendations for preventing transmission of HIV and HBV during "exposure prone invasive procedures." The CDC guidelines require all health care workers to "adhere to universal precautions, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments." The guidelines also require that health care workers comply with current guidelines for disinfection and sterilization of reusable devices used in invasive procedures." Importantly, the CDC guidelines allow medical organizations to identify which invasive procedures are "exposure-prone." *See, e.g.*, Ill. Admin. Code tit. 77 § 693.10-693.45 (1992); Ind. Admin. Code tit. 410 § 1-4 (1992); the Wisconsin Department of Health and Social Services has adopted voluntary guidelines to be enforced by the Department of Regulation and Licensing, see Recommendations for Preventing Transmission of HIV and HBV (October 28, 1992).

setting.[13] However, I fail to understand the need for separate and distinct governmental agencies to regulate the same subject matter particularly when the CDC is so eminently qualified through its knowledge, expertise, professional personnel, and continued research combined with its experience. The Supreme Court has held that a "rule is arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Ins. Co.*, 463 U.S. 29, 43 (1983). In my opinion, the failure of OSHA to take cognizance of the effectiveness and implementation of current state and federal (CDC) regulation and guidelines (including HBV vaccination statistics) leads to but one conclusion, that the final rule can and must be classified as arbitrary and capricious.

Above all, regulation of this type is just one more example of governmental waste. The much maligned health care field and its insurance systems are struggling and almost bankrupt partially because of excessive unnecessary regulations of this nature that are not only duplicative but are also less than cost efficient. OSHA further exacerbates the health care crisis when it enters into the fields of medicine, and dentistry, and related support staff, where it falls short of being either qualified or experienced to exercise regulatory oversight. My concerns about the

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[13] The observance of well-recognized infection prevention procedures greatly reduces the risk of infection to health care employees. One CDC study concluded: "There is no evidence that medical or dental workers identified by [HBV] testing who practiced good techniques will transmit hepatitis B to their patients." *Hepatitis B Transmission Between Dental or Medical Workers and Patients*, 95 Annals of Internal Medicine 229, 230 (1981). "[O]ne is left with the conclusion that a major amount of HBV transmission results from failure to observe good standards of dental and medical practice." *Id.* The CDC identified following "universal precautions including glove use" as procedures to reduce the spread of infection. There is no need for a separate federal agency (OSHA) to mandate new and unnecessary rules when appropriate standards already exist.

inefficiency of having another federal agency regulate dentists and home health employees applies with equal force to the other health care disciplines covered by the rule though they are not party to this suit. OSHA's regulation of doctors' offices (at a cost of $144 million annaually) and hospitals ($322 million) will merely duplicate the educational, investigative and research efforts of the CDC, state health agencies, hospital associations and professional organizations. This regulation upon regulation only serves to exacerbate the skyrocketing costs of health care in America.

I disagree with my two colleagues, who are both properly recognized and respected as experts in the field of economics as well as law, but who have overlooked the lack of marginal benefit in the final rule. The majority maintains that OSHA "is not authorized to . . . compare the benefits with the costs and impose the restrictions [the Bloodborne Pathogens Standard] on finding that the former exceeded the latter." Maj. Op. at 4 (citing 29 U.S.C. § 655(b)(5); *Benzene*, 448 U.S. at 642-45, 655-56; *Cotton Dust*, 452 U.S. at 509, 530-36). Accordingly, OSHA only examined "whether the restrictions *would materially reduce a significant workplace risk* to human health without imperiling the existence of, or threatening massive dislocation to, the health care industry." Maj. Op. at 4. As I have previously mentioned (*see supra* at 20), the Supreme Court has recommended that OSHA pursuant to § 3(8) of the Act, consider drafting the less costly of two equally effective proposals: "the 'reasonably necessary or appropriate' limitation might come into play as an additional restriction on OSHA to choose the [least costly regulation]." *Cotton Dust*, 452 U.S. at 514 n.32. Moreover, I am aware of no rule barring OSHA's applying reasonable judgment and fiscal responsibility. OSHA should have taken into consideration that a qualified governmental agency with a wealth of medical and scientific expertise was already responsible for the health care profession and thus OSHA could not hope to accomplish any-

thing that the CDC was unable to achieve more effectively. (Perhaps this could be achieved by congressional action giving the CDC the same inspection and enforcement powers as OSHA). Furthermore, had OSHA considered and analyzed the marginal costs and benefits of its regulations as applied to the dental, home health care and personnel services professions, they would have foregone promulgation of the rule, because less costly, less intrusive regulations are available and have effectively reduced the risk of exposure to bloodborne pathogens.

In OSHA's explanation of why the regulation is warranted, it admits: "The risk of HBV infection is most efficiently and dramatically reduced by vaccinating all workers exposed to blood and other potentially infectious materials." 56 Fed. Reg. 64036. Yet, in spite of the finding that vaccination is the most efficient preventative measure, rather than making vaccination mandatory, the government, through OSHA, proceeded to create the present bureaucratic rule which will magnify the costs of health care by over $800 million annually to consumers based upon the weak excuse that "not everyone is willing to accept the vaccine." *Id.* at 64037. The majority maintains that "the vaccine is not a hundred percent effective and, more important, . . . many health care workers refuse to be vaccinated." Maj. op. at 5. *While there are a certain number of people who refuse to be vaccinated, this certainly is not a valid reason to reject mandatory vaccination of health care workers. Thus, this argument can best be classified as a red herring. To realize that vaccinations are a reality in this day and age, one need only look to the infant children who must and do receive vaccinations before entering school and when not vaccinated are refused admission to attend classes. Other examples of compliance with mandatory vaccination programs include those traveling abroad who are denied visas or entry into certain foreign countries and the over two million men and women in the armed services.* The vast majority of dental schools are requiring proof of vaccination before

accepting incoming students as is evidenced by the increase in the percentage of incoming dental students who have received HBV vaccination from fifty-one percent in 1986 to eighty-six percent in 1988, and among dental hygiene students from sixty percent in 1986 to eight-five percent in 1988. Appendix to OSHA Brief at 44 (citing V. Merchant & J. Molinari, *The Current Status of Infection Control in North American Dental Schools* 9 (Mar. 14, 1989)). *For reasons unknown and contrary to sound medical judgment and research, OSHA concluded that even though vaccinations would reduce almost all risk of health care professionals becoming infected by HBV, the additional, far more expansive, impractical and cost inefficient precautions were necessary. Id.* at 64036-38. In part, OSHA justified the need for the entire bloodborne pathogens standard because it "will also reduce[e] the risk of infection to HIV." *Id.* at 64038. This rationale is neither scientifically nor medically established and is thus arbitrary and capricious and falls far short of being supported with substantial evidence because OSHA itself concedes *"there are no sufficient data on HIV to quantify the occupational risk of infection." Id.* (emphasis added). OSHA should not be allowed to impose on the health care industry, during these times crying for fiscal responsibility, a rule whose benefits and safeguards could be achieved through a far more cost effective and efficient means (mandatory vaccination) both to the consumer and the government alike. *See Cotton Dust,* 452 U.S. at 514, n.32 (suggesting that the "reasonably necessary or appropriate" language of § 3(8) might require OSHA to select the less expensive of two equally effective measures).

OSHA's fatal error, in my opinion, occurred when it failed to recognize and consider the varying risk of occupational exposure in the respective appellants' professions. "Infected [health care workers] who adhere to universal precautions and who do not perform invasive procedures pose *no* risk of transmitting HIV and HBV to patients." Centers for Disease Control, 40 MMWR 1, (July 12,

1991) (emphasis added). Dentists, for example, are not exposed to the same level of risk as other health care workers such as surgeons, nurses or other medical personnel in large metropolitan hospital's emergency or operating rooms, just as cotton gin workers are not exposed to the same risk as are other cotton industry employees. A large number of dentists both in general practice and in a number of specialties, unlike surgeons in hospital settings, have little exposure to blood. *See* ADA Brief at 10.[14] Despite the testimony of over 400 witnesses and an additional 3000 written comments, before this court, OSHA relies on but one single 1988 article (*Infection control recommendations for the dental office and the dental laboratory*, 116 J.A.D.A. 241 (Feb. 1988)) to support its claim that dental workers are at risk of acquiring HBV. OSHA Brief at 18. The article fails to take into account the most recent safeguard innovations such as the increased use of the HBV vaccine by the dental and medical professionals, and the implementation of recent CDC Guidelines.[15] OSHA argues that having to condust a significant risk analysis for each industry would hamper its ability to regulate.[16] This

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[14] I recognize the possibility of occupational exposure to bloodborne pathogens in a dentists' office. However, a dentist's risk is far less than that of that of other health care professionals, such as orthopedic, heart, vascular or neurosurgeons, and thus they are less susceptible to occupational exposure to bloodborne pathogens. The dentist normally operates in a controlled environment (90% of patients have an appointment as contrasted with a hospital emergency room) and thus knows what to expect and/or how to prepare the staff for possible exposure to infection from any given patient as well as knowing when and where to wear gloves or a mask if necessary in the exercise of acceptable medical judgment. OSHA appendix at 48 (citing 1988 ADA survey).

[15] The risk of exposure is also reduced because many dentists now use aspirators placed directly in the oral cavity that continually withdraws the blood seeping from the puncture or laceration of gum tissue thus eliminating to a great extent the chance of exposure to the dentist or employees. OSHA appendix at 50.

[16] OSHA relies on *Associated Builders and Contractors, Inc. v. Brock*, 862 F.2d 63, 68 (D.C. Cir. 1988), *cert. denied*, 494 U.S. 1003

is another example of OSHA's less than scientific approach to drafting this rule, for I firmly believe that in the interest of fairness to the professions it is incumbent that OSHA undertake a thorough risk analysis and not merely rely on estimates. Moreover, OSHA's argument that its rule making will be hampered is undermined by the fact that much of the statistical material (including the research necessary to produce a significant risk analysis) was either in the hands of or readily available to OSHA.

OSHA attempts an end run around the significant risk/benefit issue by arguing that the dental industry does not have a "zero risk" (and I might add who does—the unregulated barber, the cosmetologist?). This argument is without merit because it completely disregards and casts aside the burdens established in *Benzene*. *Benzene* requires OSHA to make a finding that the employees to be regulated are exposed to a *significant risk*. 448 U.S. at 642, 100 S. Ct. at 2864. *Benzene* does not require that the appellants establish a "zero risk" in their professions. There may well be a danger of transmitting infection in the dental and home health environments but it is neither scientifically nor medically established in the record before us. Therefore, if Congress fails to intervene, the reasoned and proper judgment of the court should as a last resort be to remand the final bloodborne pathogens standard to OSHA with directions to determine whether a *significant risk exists* when considering the various appellants' pro-

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(1990), which held "[a] requirement that the Secretary assess risk to workers and need for disclosure with respect to each substance in each industry would effectively cripple OSHA's performance of the duty imposed on it . . . ." OSHA's reliance on *Associated Builders* is misplaced because that case involved "thousands of chemical substances used in numerous industries," *id.*, the bloodborne pathogens standard only involves one substance (blood) and only a handful of distinct sectors. Clearly disaggregation would have been possible and appropriate.

For a brief discussion of the problems posed by OSHA inspectors seeking to enforce the rule see *infra* at 48.

fessions individually. OSHA must also determine and explain whether the final rule results in *significant benefits* through the use of recognized empirical data.

IV. *PROTECTION FOR THE EMPLOYEE BUT NOT THE PATIENT*

The appellants also argue that the OSHA regulations fail to consider the very important interests of the consumer-patient in knowing whether his health care provider is infected with a bloodborne disease thus permitting the patient to make an informed and reasonable judgment as to whether they wish to discontinue treatment with the infected practitioner or a member of his staff. The appellants stress that the CDC Guidelines, while not requiring health care workers to be tested for viruses, do require (relying on the honor system) that infected workers report to a health care committee for recommendation as to whether they may perform invasive procedures. The CDC Guidelines *also properly recommend that infected health care workers inform patients of their infected status* before *performing invasive procedures*:

> "HCWs who are infected with HIV or HBV . . . should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and have been advised under what circumstances, if any, they may continue to perform these procedures. *Such circumstances would include notifying prospective patients of the HCW's sero positivity before they undergo exposure-prone invasive procedures.*"

Centers for Disease Control, 40 MMWR 5 (July 12, 1991) (emphasis added) footnote omitted).[17]

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[17] *Additionally, the American Medical Association and the American Dental Association have recommended that HIV-infected personnel should refrain from performing invasive procedures.* Karen C. Lieberman & Arthur R. Derse, *HIV-Positive Health Care Workers and the Obligation to Disclose: Do Patients Have a Right to*

I am well aware that many individuals in the medical community oppose disclosure of a health care professional's HIV status. I disagree with their point of view for I believe the consumer-patient's interest is paramount for he or she is entitled to be made aware of this information in order that they might make an informed health care decision before undergoing any medical or dental procedure (if indeed there is a risk of HIV or HBV infection as OSHA contends). A primary reason many medical professionals oppose disclosure is that they are interested in protecting their fellow professionals whose practices might decline or cease to exist if patients knew their physician or treating health care worker was afflicted with an infectious disease. This practice is contrary to the response the medical community and public health officials take toward infected food workers (requiring medical treatment and prohibiting employment, *see infra* at 40). The opposition to disclosure does not stem from a concern for the consumer-patient who merely seeks to make an informed health care decision.

I understand OSHA's congressionally delegated responsibility is to protect employees, in doing this however, OSHA completely cast aside the interest of the consumer-patient and focused exclusively on the confidentiality interests of the health care employees. OSHA rationalizes this by stating that confidentiality of records will encourage employees to report exposure incidents (I disagree that it will *encourage* reporting but it might conceivably make employees somewhat less inhibited to report exposures). 56 Fed. Reg. 64160. After an "exposure incident" [18] to patient blood or other potentially infectious

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Know?, 13 J. Legal Medicine 333, 339 (1992). It seems quite obvious that the CDC, state agencies and professional organizations (who are more qualified than OSHA) should establish the regulations and guidelines that govern the health care profession.

[18] "*Exposure incident* means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or

material like saliva,[19] the rule requires employers to provide confidential blood testing from a health care professional for their employees. Importantly, in § 1910.1030 (f)(5)(ii) of the bloodborne pathogens standard "the healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

> "(A) that the employee has been informed of the results of the evaluation; and
>
> "(B) that the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.
>
> "(iii) *All other findings or diagnosis shall remain confidential and shall not be included in the written report.*"

Bloodborne Pathogens Standard § (f)(5)(ii)-(iii) (emphasis added).

In the record-keeping section, the final rule states:

> "(h)(1)(i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 C.F.R. 1910.20. . . .
>
> "(iii) Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

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other potentially infectious materials that results from the performance of an employee's duties." 56 Fed. Reg. 64175 (quoting § 1910.1030(b) of the Bloodborne Pathogens standard).

[19] There are reputable commentators *who maintain that saliva, rather than transmitting HIV, may actually inhibit its transmission.* P. Fox, et al., *Salivary Inhibition of HIV-1 Infectivity: Functional Properties and Distribution in Men, Women and Children,* 118 J. Am. Dental Assoc. (JADA) 709 (1989).

"(A) Kept confidential; and

"(B) Are not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law."

Id. § (h)(1)(i)-(iii).

The meaning of the language "as may be required by law" is indefinite, yet OSHA argues that § (h)(1)(iii)(B) permits disclosure of employee records as required by state law (inferring patients somehow may be able to acquire information necessary to granting informed consent). Interestingly though, even if the record is open to inspection as OSHA alleges, the record fails to contain any information dealing with the employee's infection status (positive or negative), because § (f)(5)(b)(iii) of the bloodborne pathogens standard prohibits the employee's health record from revealing such information. This rule denying the consumer-patient valuable information flies directly in the face of the professional norms in the health care industry (which is bound by the common law of informed consent)[20] and defies objectivity, fairness

[20] Lieberman & Derse, *supra* note 17, document the cases giving rise to the common law right to informed consent and conclude that a patient has a right to know whether his health care provider is HIV-infected. *Id.* at 342-456. "As a further consideration, even if it is assumed that the risk of transmission from health care worker to patient drug during an invasive procedure is quite low, various courts have held that the fact a risk is remote will not always negate the duty to disclose under the informed consent doctrine." *Id.* (citations omitted). "The fact that the health care professions themselves are uncertain about the degree of risk to patients is all the more reason why patients should be in a position to decide for themselves whether to accept the risk, as the courts have held." *Id.* at 348 n.91. "While the risk of transmission of HIV from health care worker to patient during an invasive procedure may be low, the consequence of the occurrence of that risk at this time appears invariably to be death." *Id.* at 350. "When a health care worker permits a patient to be placed at risk in order to obtain personal benefit, even when the risk is as potentially re-

and common sense.[21]

The courts have long recognized the right of a patient to determine what medical procedures he or she will undergo, *see, e.g., Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 110 S. Ct. 2841, 2851 (1990); *Schloendorff v. Society of New York Hosp.*, 105 N.E. 92, 93 (N.Y. 1914); and therefore a health care professional may not deny information relevant to making an informed decision as to a medical or dental procedure. Lieberman & Derse, *supra* note 17 at 342 (citing *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 317 P.2d 170, 181 (Cal. App. 1957) ("A physician violates his duty to his patient . . . if he withholds any facts which are necessary to form the basis of an intelligent consent . . . . Likewise, the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent.")).

The confidentially provision also conflicts with a dentist's ability to prudently and effectively manage his office. State statutes permit a health care provider to inform his staff assisting him in providing care to a patient if that patient is HIV positive to ensure extra precaution. *See, e.g.*, Ill. Ann. Stat. ch. 111½ para. 7309(c) (Smith-Hurd 1988); Wis. Stat. Ann. § 146.025(5) (West 1989). So too should a dentist, physician, surgeon, hospital administrator or other health care professional be entitled to know whether an employee in his office is infected, thus presenting a risk to himself as well as his patients, or

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mote as transmitting HIV to an uninfected patient, the health care worker's interests conflict with those of the patient [in violation of the fiduciary duty]." *Id.* at 353.

[21] Eighty-six percent of adults surveyed in a Gallup Poll said patients "should be told if the health care worker caring for them has AIDS." Larry Gostin, *Hospitals, Health Care Professionals, and AIDS: The "Right to Know" the Health Status of Professionals and Patients*, 48 Md. L. Rev. 12, 14. Without such information, a patient who is infected by a health care professional could unwittingly spread the infection to others.

fellow employees by exposing them to the risk of infection during a procedure. Certainly it cannot be labeled discrimination when enacting rules and/or regulations that prevent one with a communicable virus from spreading that infectious virus to an uninformed, trusting consumer. *See* Americans with Disabilities Act 42 U.S.C.A. § 12113 (b) (West. Supp. 1992) ("The term 'qualification standards' may include a requirement that an individual shall not pose a direct threat to the health or safety of other individuals in the workplace.").[22] Public health officials, when informed, have the responsibility to see that a food worker infected with either the hepatitis A virus or the tuberculosis virus is barred from employment in all aspects of the food industry. *Id.* § 12113(d). Do not justice and logic dictate that the same measures be taken to prevent a health care employee with a bloodborne virus from exposing a patient to infection? Does not the consumer have at least equal rights to protection against infection as the health care provider has? It is evident that the quagmire of regulations from OSHA, the CDC, state agencies and professional organizations yield a confusing morass of conflicting intentions, goals, rules and regulations.

The root of much of this dispute is a *vocal minority's emphasis on the rights of the individual at the expense of the common good of all.* The defeat of the congressional attempt to require mandatory testing of health care workers can only be expalined by powerful lobbying efforts. *See generally* William B. Rubenstein, *Law and Empowerment: The Idea of Order in the Time of AIDS*, 98 Yale L.J. 975, 993-94 (1989) (book review discussing

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[22] OSHA's Bloodborne Pathogens Standard makes no provision for an employer to be made aware of his employee's health status through a documented record or health report even when the employee may suffer from fatigue and thus render a less than professional performance or expose himself or another to danger because of HBV or HIV infection.

impact of lobbyists). It is incumbent upon Congress to address and take an in-depth look at the AIDS problem and achieve a balance that reflects the paramount interest of all mankind and not let the overriding concern be with the individual's right of privacy.

Additionally, OSHA is attempting to regulate a "toxic substance" (human blood) which is unique from all other areas of OSHA regulation yet it lacks the required expertise, knowledge or experience in the highly specialized field of health care to evaluate the necessary scientific, medical, and/or dental data. *See, State of Wisc., Dep't of Health v. Bowen,* 797 F.2d 391, 412 (7th Cir. 1986) (Coffey, J., dissenting) ("Nameless, faceless, lay government officials have neither the knowledge of the patient's needs, the medical training, nor the authority to" intrude into medical and dental procedures.). OSHA was originally created to protect the workers in the factory and construction environments and, as a result of knowledge and experience is well-equipped to regulate those industries, but I have very serious doubts about their qualifications to monitor the health care field, including but not limited to dentists, doctors and hospitals. *See* OSH Act of 1970, P.L. 91-596, 1970 U.S.C.C.A.N (91 Stat.) 5177, 5178-81 (discussing industrial risks and never mentioning the health care profession). I suggest that the Congress reexamine OSHA's role in regulating the highly technical health care sector and see if that area might better be served by an agency or agencies possessing the required expertise in the discipline, such as the Centers for Disease Control in the Department of Health and Human Services and the respective qualified state controlled agencies and professional organizations. The CDC has been investigating, compiling data, and dealing with the health risks in the workplace for years and in turn disseminates its findings as well as this vital health care information throughout the nation. State health agencies frequently use this information along with the CDC guide-

lines to aid in the states' regulation of the health care profession. Because the states have the capability of contemporaneous oversight and timely inspections, they have traditionally regulated health care, and thus have acquired a tremendous amount of experience and expertise in the field. Consequently, it is both unnecessary and wasteful for OSHA to usurp the functions of the CDC and the states in health regulation. Having OSHA defer to the CDC and state health agencies when regulating health care is similar to the government's leaving nuclear regulation to the Nuclear Regulatory Commission, (it would be absurd for the inexperienced OSHA inspectors to regulate the nuclear workplace environment and the employees of power plants, arms production or nuclear waste facilities). I am of the opinion that allowing OSHA inspectors, who lack the necessary knowledge and expertise, to regulate and intrude into the highly technical medical procedures of the 20th and 21st centuries is at best extremely suspect.

In a typical workplace, such as a factory, government regulation limits an employee's exposure to toxic materials like lead or asbestos. These regulations are designed to benefit the worker only and not impact third parties. In reality though, there is an indirect impact on the consumers who are required to pay the higher price for the product affected by the unnecessary piling on of needless and ineffective regulations on top of regulations. In the health care field, however, the third party (the innocent uninformed consumer-patient) is directly exposed and impacted by the regulations with possible fatal consequences (according to OSHA). For this reason, OSHA, in the exercise of logic, common sense and fairness should have also considered the interest of the patient and sought to protect the consumer-patient from possible harmful exposure to bloodborne viruses. *Because the final rule fails to consider the health care consumer, it is flawed and cries out for judicial and/or congressional intervention*

to weigh and balance the documented concerns and protect the innocent and uninformed health care consumer as well as the employees.

Further evidence that the regulations fail to consider the preeminent interests of patients is found in the excessive record keeping requirements imposed on health care employers (thirty years beyond an employee's tenure with the employer).[23] This thirty-year record keeping requirement will have little or no impact on reducing the spread of infectious diseases in the health care industry, rather it merely creates another administrative nightmare and increases the already prohibitive cost of purchasing medical and dental services. OSHA estimated the annual cost of record keeping alone to be in excess of $17 million. 56 Fed. Reg. 64064. This figure, in all probability, fails to include costs for increased clerical needs, storage facilities or the time of health care professionals interfering with patient care and valuable research. Despite well-supported objections to the thirty-year record keeping requirement, OSHA cavalierly concluded:

> "that this provision is neither excessive nor impractical when viewed from the perspective of the employee. Vaccination records are an essential part of an employee's medical history. OSHA believes that retention of these records and exposure incident rec-

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[23] OSHA rationalizes the thirty year requirement by stating: "Retaining medical records for the period of employment plus thirty years is necessary because hepatocellular carcinoma, which can occur as a result of hepatitis B infection can, and indeed commonly does, take twenty to thirty years to develop. Individuals who become HBV carriers or develop chronic hepatitis are often ill and infected for the rest of their lives. Moreover, OSHA believes this is an appropriate time period, in light of the fact, that 5% of those exposed to HIV infected blood do not seroconvert within six (6) months. Finally, the time period for retention of records is consistent with other OSHA standards requiring retention of occupational medical records."

56 Fed. Reg. at 64171.

> ords is necessary to assist current and future health care professionals in assessing an employee's medical history and prescribing medical treatment."

56 Fed. Reg. at 64171. This reasoning lacks concern for the provider as well as the consumer-patient who bears the cost without a recognizable benefit.

Viewing this provision as applied to temporary services reveals its true absurdity. Because many temporary medical personnel serve more than one temporary services employer (often for less than a week and sometimes for but a day), each employer is required to incur the added expense of maintaining and storing duplicative records of each employee for a period of thirty years. This requirement could have been eliminated or more properly transferred by placing the responsibility on the employee. Requiring health care employees to carry a health card revealing recorded vaccinations, known exposure incidents and any other pertinent information would eliminate a large portion if not the majority of the estimated $17 million in paperwork and poses no more burden on an employee than carrying a drivers license, a permit, social security card, or charge card. Moreover, it is in the employee's best interests to have this vital information in record form in his or her possession in case of medical emergency or future employment. As the majority maintains, the profession could regulate itself because "health care workers have a stronger incentive than the government to protect themselves from health hazards at a reasonable cost . . ." Maj. Op. at 6. The regulation, however, reflects an agency decision to make society bear the costs of individuals who do not want to be inconvenienced. OSHA, for reasons unexplained in this record, ill-advisedly chose to impose the costs for medical records of employees (who allegedly do not want to be inconvenienced by vaccinations or maintaining personal vaccination records) on the already financially strained health care consumer.

V. *FEASIBILITY*

Section 6(b)(5) of the OSH Act requires that final regulations be feasible. The figures that OSHA used to conduct the feasbility analysis were flawed resulting in a misleading and foundationless economic picture. I agree that the cost effects of the final rule are understated as the majority observes. Maj. Op. at 5-6 (discussing understated "time costs" [24] of compliance and the number of lives the rule will save). Additionally, a significant oversight in the feasibility analysis is that the majority of dental patients directly pay for their own dental expenses due to the limited coverage of dental insurance and its high cost. Therefore, dentists will in all probability be unable to pass on the costs of complying with the rule as readily as doctors or hospitals (who serve a greater percentage of patients with insurance coverage), because patients without insurance will defer or forego dental treatment rather than pay the higher cost. ADA Brief at 38-39; OSHA appendix at 46. Obviously, dental practitioners, like businessmen, either absorb the costs or pass them on to their patients. In an era of decreasing demand for dental services (dental school closings result in fewer dentists practicing, H. Barry Waldman, *Dental School Demographics: More than Just Decreases in the Overall Number of Students*, 57 J. Am. Coll. Dentists 22 (1990)), the vast majority of dentists should not be put in the position of having to bear additional costs of unnecessary govern-

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[24] One example of understated time costs concerns those practicing in Pediatric Dentistry. The ADA has argued that a child may be traumatized by the sight of a dentist wearing goggles and a mask. This argument only scratches the surface of the real problem. A dentist wearing goggles and a mask may have to take more time to calm a child (especially one in for emergency treatment because of an injury) before instituting treatment. Those children needing to be calmed frequently must undergo a general anesthesia rather than a topical anesthesia. This increases the risk to the child as the number of assistants necessary to position and monitor the child patient, the cost, and the potential liability to the dentist as well as increasing the time to conduct the procedure.

mental regulation. The combination of fewer practicing dentists along with the impact of the OSHA rule can only produce an increase in fees for dental services. The majority mentions that OSHA and the Dental Association have "ignored" the "time costs" of the rule. Maj. op. at 9-10. I would not classify the Dental Assocation's brief as ignoring the time cost (Appellants Brief at 40-41) but I agree they failed to quantify and itemize those costs. Nonetheless, the consumer will ultimately bear the burden of the increased costs of providing dental services.

Another example of the flawed feasibility analysis is that OSHA failed to include disposal costs of non-reusable personal protective equipment (PPE) or laundry costs for reusable PPE. 56 Fed. Reg. 64065 (OSHA includes no cost for laundering reusable gowns and only $.32 per dental office as the annual cost of bags for disposable gowns and PPE). In 1987, the CDC stated "[a]lthough soiled linen has been identified as a source of large numbers of certain pathogenic microorganisms, the risk of actual disease transmission is negligible. Rather than rigid procedures and specifications, hygienic and commonsense storage and processing of clean and soiled linen are recommended." CDC, 36 MMWR at 11S (August 2, 1987). Despite this CDC finding concerning laundry, OSHA has created stringent laundering regulations. 56 Fed. Reg. 64178. The ADA has estimated the annual cost of laundering reusable PPE at $115 million [25] which

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[25] Additionally, the estimated cost of reusable gowns is approximately $28 million, resulting in a total cost of $143 million to satisfy the laundering regulations. OSHA did not prepare any cost estimates on the cost of the purchasing and laundering reusable fabric gowns. 56 Fed. Reg. 64065; ADA Appendix at 220.

This court attempted, though unsuccessfully, to resolve the confusion between the ADA's laundering estimate during the rule making procedure and the estimate in their brief before this court. Unfortunately, we have only an index of documents filed during the rule making and any cost estimates derived subsequent to the rule making procedure are inadmissible.

exceeds all the costs of compliance with the regulations that OSHA identified for the whole dental profession.[26] OSHA responds that because of the high costs of laundering, most dental practitioners would decide to employ disposable protective equipment. For some reason, OSHA failed to factor in the costs of storing and disposing of such waste but should have for I know of very few dental practitioners with an incinerator or the facilities to store and transport infectious waste to an incinerator in their respective office buildings. 56 Fed. Reg. 64065. Additionally, OSHA estimated the cost of a disposable gown at $.32 while the ADA estimates the actual cost of a fluid resistant gown is $2.50. OSHA appendix at 64.[27] These oversights certainly call into question whether the rule is supported by substantial evidence.[28] I disagree with the

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[26] Some confusion exists as to cost estimates because the rule applies only to employees. For the purpose of the rule, a dentist who has incorporated his or her practice (S.C.), probably for tax purposes, is considered an employee of the corporation while a dentist who has not incorporated is not an employee and thus not covered under OSHA. Therefore, OSHA can minimize the costs of complying with the rule by only including the costs of those dentists who are employees of corporations.

[27] In their brief before OSHA responding to the proposed bloodborne pathogens standard, the ADA estimated the cost of compliance with the rule to be $524,541,564. OSHA appendix at 49-50. OSHA's estimate that the rule will increase costs of health care by $817 million annually is certainly an understatement. More importantly though, considering the fact that the states, the CDC and the professional groups are and have been regulating for a period of time, could not these same dollars be more wisely spent on research to halt the deadly effects of heart disease, cancer, stroke and AIDS?

[28] Another omission in the feasibility analysis is the failure to include any costs for complying with the OSHA engineering standards in §§ (d) (2) (iii), (d) (4) (iii) (B) requiring employers to make sinks readily accessible for hand washing (irrespective of the fact the states already have similar regulations) and ensuring proper storage of regulated waste. 56 Fed. Reg. 64065. A final example of the flawed feasibility analysis is OSHA's estimate that the proce-

majority that the omitted costs, such as the thirty-year record-keeping and laundering requirements, are "not enough to make a decisive difference." Maj. op. at 12. Only a complete and accurate feasibility study will determine whether the rule is warranted.

Regarding the temporary medical personnel services, the feasibility analysis is likewise misleading. OSHA calculated an annual turnover rate among registered nurses between 12.9 and 21.8 percent and among licensed practicing nurses and nurses aides between 22.5 and 36.3 percent. The temporary services sector, however, has turnover rates from three to five times greater than the rest of the profession. HHSSA appendix at 2 (testimony of James Keefe, Sept. 21, 1989, on bloodborne pathogens standard, Exhibit 55). Many temporary service employees work as briefly as one week for an employer and the majority are employed by the same employer for less than six months. *Id.* Such a disparity in turnover rates certainly negates the accuracy of OSHA's feasibility analysis and calls into question the validity of the rule as applied to the temporary services field.

Finally, OSHA fails to enumerate how it intends to enfoce this standard. Do they intend to invade the privileged relationship between a doctor and/or dentist and his or her patient? Do they intend to hire thousands of new inspectors to enforce this rule? We now have over three million civilian federal employees—do we need more? Are they going to transfer the inspection responsibility to the states along with all the enforcement ex-

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dure following an employee's exposure to bloodborne pathogens, § (f) (3), would only take 20 minutes. For a hospital employee (with immediate access to a physician) this may be reasonable, but for a dental worker this procedure would more likely take one-half day traveling to and from the office in addition to the waiting time, time for taking the medical history including information concerning the exposure incident, as well as the time for testing procedure in the physician's office. This would amount to 12-14 lost work days per year. OSHA appendix at 71-72.

pense? Do they expect voluntary compliance which all too frequently results in universal disregard for the law?

VI. *CONCLUSION*

I am cognizant of the need for dental and medical regulations and safeguards to insure and prevent the spread of infection, but fail to understand why OSHA must assert authority over the health care field when it lacks the required medical knowledge, training, and experience, much less expertise. In the absence of proof that the CDC Guidelines are inadequate, any regulation by OSHA is unnecessarily dupliactive of CDC efforts and merely serves to increase health care costs with little if any corresponding benefit. Moreover, OSHA's method of attempting to satisfy the significant risk standard was less than desirable. OSHA should have disaggregated each of the health care disciplines, in particular, the larger ones, including hospitals (2.3 million employees), physicians' offices (640,000 employees), and dental offices (316,000 employees) (*see supra* note 5 listing the twenty-four sectors covered by the rule), in order to accurately determine if a significant risk of exposure exists in the particular field and whether the rule results in significant benefits to the particular discipline. Combining the millions of health care workers into one group and then merely relying on estimates of risk is a less than acceptable manner of regulating the nearly five million health care workers in this country.

The majority dismisses out of hand several valid ADA arguments, maj. op. at 12, such as the burden of the thirty-year record-keeping requirement, costs of laundering and difficulties of complying with the post-exposure procedures. I have attempted to address some of these issues in order to present a more complete analysis should Congress decide to take an in-depth look at this problem to determine if OSHA should exercise its authority in the same realm as the CDC and the State health agencies. If Congress concludes there is a need for two fed-

eral agencies—in addition to state agencies and professional organizations—to exercise oversight in the health care field, then Congress must acknowledge their responsibility for increasing the cost of health care.

Should Congress after due deliberation and debate express its desire for more regulation of health care, then OSHA, with the exercise of proper judgment, could draft a very concise regulation designed to protect employers, employees and patients and segregate the different areas of health care. The most effective and cost-efficient regulation would be to require HBV vaccinations for all health care workers at risk of exposure in the United States, and to enforce existing state regulations, the 1991 CDC Guidelines (requiring universal precautions), and the OSHA general personal protective equipment rules. 29 C.F.R. 1910.132(a). Such a rule would eliminate nearly any potential of a health care worker contracting an infectious disease in the workplace as well as demonstrating proper fiscal responsibility on the part of the government. As previously mentioned, OSHA itself acknowledges that HBV vaccinations are 96 percent effective at preventing infection. Not only would such a rule be far more effective than the proposed rule, the costs of this regulation would be dramatically reduced from that proposed by OSHA.

There is no need for four separate entities (OSHA, CDC, state agencies, and professional organizations) to regulate the health care industry based on one suspected case of a dentist becoming infected with HIV through work related exposure. One qualified entity can most effectively and efficiently regulate the health care profession. I see no reason why the respective states are unable to continue to regulate the medical and dental profession as the states have traditionally done in the past and presently do in many other professional fields including but not limited to law, engineering and architecture.

> "It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power. The state's discretion in that field extends naturally to the regulation of all professions concerned with health."

Barsky v. Board of Regents, 347 U.S. 442, 449 (1954), *see also State of Wisc., Dep't of Health v. Bowen*, 797 F.2d 391, 413 (7th Cir. 1986) (Coffey, J. dissenting). Furthermore, OSHA may be highly qualified to regulate everything from construction and manufacturing to the foundations of the high trapeze act in the circus, but I am of the opinion that as presently constituted it is unqualified to regulate fields of medicine and dentistry and their supporting staffs.

Finally, there is little doubt that lobbyists and the media in all probability have greatly impacted OSHA's rule making. Sadly, while billions of dollars are and will be spent enforcing OSHA's bloodborne pathogen standard as presently drafted (merely duplicating the research and oversight of other qualified agencies), these same funds could be more wisely expended to aid the millions of Americans who continue to die from the nation's three leading killers (heart disease, cancer, and stroke) as well as AIDS and other diseases.[29]

A true Copy:

Teste:

Clerk of the United States Court of
Appeals for the Seventh Circuit

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[29] *See, e.g.*, Budget of the United States Government (Fiscal Year 1993). Part One at 113-115, U.S. Government Printing Office (1992).

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RULES AND REGULATIONS

XI. The Standard

General Industry

Part 1910 of title 29 of the Code of Federal Regulations is amended as follows:

PART 1910—[AMENDED]

Subpart Z—[Amended]

1. The general authority citation for subpart Z of 29 CFR part 1910 continues to read as follows and a new citation for § 1910.1030 is added:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736), as applicable; and 29 CFR part 1911.

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Section 1910.1030 also issued under 29 U.S.C. 653.

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2. Section 1910.1030 is added to read as follows:

§ 1910.1030 Bloodborne Pathogens.

(a) *Scope and Application.* This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) *Definitions.* For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

Blood means human blood, human blood components, and products made from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or

remove the bloodborne pathogens hazard from the work-place.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials means

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or

other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing

homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

(c) *Exposure control*—(1) *Exposure Control Plan.* (i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

(ii) The Exposure Control Plan shall contain at least the following elements:

(A) The exposure determination required by paragraph (c)(2).

(B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-Up, (g) Communication of Hazards to Employees, and (h) Recordkeeping of this standard, and

(C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

(v) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

(2) *Exposure determination.* (i) Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

(A) A list of all job classifications in which all employees in those job classifications have occupational exposure;

(B) A list of job classifications in which some employees have occupational exposure, and

(C) A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

(ii) This exposure determination shall be made without regard to the use of personal protective equipment.

(d) *Methods of compliance*—(1) *General*—Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

(2) *Engineering and work practice controls.* (i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

(ii) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(iii) Employers shall provide handwashing facilities which are readily accessible to employees.

(iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

(v) Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

(vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

(vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

(A) Contaminated needles and other contaminated sharps shall not be recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure.

(B) Such recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

(viii) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

(A) Puncture resistant;

(B) Labeled or color-coded in accordance with this standard;

(C) Leakproof on the sides and bottom; and

(D) In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohbiited in work areas where there is a reasonable likelihood of occupational exposure.

(x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

(xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

(xii) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

(xiii) Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

(A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph

(g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

(B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

(C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

(xiv) Equipment which may become contaminated with blood or other potential infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

(A) A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

(B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

(3) Personal protective equipment—(i) Provision. When there is occupational exposure, the employer shall

provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

(ii) Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

(iii) Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

(iv) Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

(v) Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

(vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

(vii) All personal protective equipment shall be removed prior to leaving the work area.

(viii) When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(ix) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

(A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

(B) Disposable (single use) gloves shall not be washed or decontaminated for re-use.

(C) Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

(*1*) Periodically reevaluate this policy;

(*2*) Make gloves available to all employees who wish to use them for phlebotomy;

(*3*) Not discourage the use of gloves for phlebotomy; and

(*4*) Require that gloves be used for phlebotomy in the following circumstances:

(*i*) When the employee has cuts, scratches, or other breaks in his or her skin;

(*ii*) When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

(*iii*) When the employee is receiving training in phlebotomy.

(x) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

(xi) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

(xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopeadic surgery).

(4) *Housekeeping.* (i) General. Employers shall ensure that the worksite is maintained in a clean and sani-

tary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

(ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

(B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

(C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

(E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to

reach by hand into the containers where these sharps have been placed.

(iii) Regulated Waste.

(A) Contaminated Sharps Discarding and Containment. (*1*) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

(*i*) Closable;

(*ii*) Puncture resistant;

(*iii*) Leakproof on sides and bottom; and

(*iv*) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

(*2*) During use, containers for contaminated sharps shall be:

(*i*) Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

(*ii*) Maintained upright throughout use; and

(*iii*) Replaced routinely and not be allowed to overfill.

(*3*) When moving containers of contaminated sharps from the area of use, the containers shall be:

(*i*) Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

(*ii*) Placed in a secondary container if leakage is possible. The second container shall be:

(*A*) Closable;

(*B*) Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

(*C*) Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

(*4*) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

(B) Other Regulated Waste Containment. (*1*) Regulated waste shall be placed in containers which are:

(*i*) Closable;

(*ii*) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

(*iii*) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(2) If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

(*i*) Closable;

(*ii*) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

(*iii*) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

(*iv*) Closed prior to removal to prevent spillage or protrusions of contents during handling, storage, transport, or shipping.

(C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

(iv) Laundry.

(A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. (1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

(2) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

(3) Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

(B) The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

(C) When a facility ships contaminated laundry offsite to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

(e) *HIV and HBV Research Laboratories and Production Facilities.* (1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the

analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

(2) Research laboratories and production facilities shall meet the following criteria:

(i) Standard microbiological practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(ii) Special practices.

(A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

(B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

(C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

(E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

(F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

(G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

(H) Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as antoclaving known to effectively destroy bloodborne pathogens.

(I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

(J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

(K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

(L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

(M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(iii) Containment equipment. (A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

(B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

(3) HIV and HBV research laboratories shall meet the following criteria:

(i) Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

(ii) An autoclave for decontamination of regulated waste shall be available.

(4) HIV and HBV production facilities shall meet the following criteria:

(i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of

the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

(ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

(iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(iv) Access doors to the work area or containment module shall be self-closing.

(v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional ariflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, and shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

(5) *Training Requirements.* Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

(f) *Hepatitis B vaccination and post-exposure evaluation and follow-up—(1) General.* (i) The employer shall make available the hepatitis B vaccine and vaccination

series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

(ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

(A) Made available at no cost to the employee;

(B) Made available to the employee at a reasonable time and place;

(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

(D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

(iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

(2) *Hepatitis B Vaccination.* (i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occuptional exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

(ii) The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

(iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the

standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

(iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in appendix A.

(v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(3) *Post-exposure Evaluation and Follow-up.* Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

(i) Documentation of the route(s) of exposure, and the circumstances under which the exposure- incident occurred;

(ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(C) Results of the source individual's testing shall be made available to the exposed employee, and the em-

ployee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(iii) Collection and testing of blood for HBV and HIV serological status;

(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(v) Counseling; and

(vi) Evaluation of reported illnesses.

(4) *Information Provided to the Healthcare Professional.* (i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

(ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

(A) A copy of this regulation;

(B) A description of the exposed employee's duties as they relate to the exposure incident;

(C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(D) Results of the source individual's blood testing, if available; and

(E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

(5) *Healthcare Professional's Written Opinion.* The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

(i) The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

(ii) The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

(A) That the employee has been informed of the results of the evaluation; and

(B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(6) *Medical recordkeeping.* Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) *Communication of hazards to employees*—(1) *Labels and signs.* (i) Labels. (A) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

(B) Labels required by this section shall include the following legend:

BIOHAZARD

BIOHAZARD

(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color.

(D) Labels required by affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels.

(F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(I) Regulated waste that has been decontaminated need not be labeled or color-coded.

(ii) Signs. (A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Labortory and Production Facilities, which shall bear the following legend:

BIOHAZARD

(Name of the Infectious Agent)

(Special requirements for entering the area)

(Name, telephone number of the laboratory director or other responsible person.)

(B) These signs shall be fluorescent orange-red or predominantly so, with lettering or symbols in a contrasting color.

(2) *Information and Training.* (i) Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

(ii) Training shall be provided as follows:

(A) At the time of initial assignment to tasks where occupational exposure may take place;

(B) Within 90 days after the effective date of the standard; and

(C) At least annually thereafter.

(iii) For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

(iv) Annual training for all employees shall be provided within one year of their previous training.

(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(vii) The training program shall contain at a minimum the following elements:

(A) An accessible copy of the regulatory text of this standard and an explanation of its contents;

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(C) An explanation of the modes of transmission of bloodborne pathogens;

(D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

(E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

(G) Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

(H) An explanation of the basis for selection of personal protective equipment;

(I) Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administra-

tion, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

(J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

(M) An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

(N) An opportunity for interactive questions and answers with the person conducting the training session.

(viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

(A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

(C) The employer shall provide a training program to employees who have no prior experience in handling hu-

man pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) *Recordkeeping—(1) Medical Records.* (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

(A) The name and social security number of the employee;

(B) A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

(C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

(D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

(E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

(iii) Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

(A) Kept confidential; and

(B) Are not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by pargraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

(2) *Training Records. (i) Training records shall include the following information:*

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

(D) The names and job titles of all persons attending the training sessions.

(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(3) *Availability.* (i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(4) *Transfer of Records.* (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

(i) *Dates—(1) Effective Date.* The standard shall become effective on March 6, 1992.

(2) The Exposure Control Plan required by paragraph (c)(2) of this section shall be completed on or before May 5, 1992.

(3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

Appendix A to Section 1910.1030—Hepatitis B Vaccine Declination (Mandatory)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

[FR Doc. 91-28886 Filed 12-2-91; 8:45 am]

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

Docket No. 91-3865
(12/19/91)

AMERICAN DENTAL ASSOCIATION,
Petitioner,

v.

LYNN MARTIN, SECRETARY OF LABOR, THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, UNITED STATES DEPARTMENT OF LABOR,
Respondent.

PETITION FOR REVIEW

Pursuant to Section 6(f) of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(f), and Rule 15 of the Federal Rules of Appellate Procedure, the American Dental Association hereby petitions this Court for review of the final rule for "Occupational Exposure to Bloodborne Pathogens," 29 C.F.R. § 1910.1030 promulgated by the Occupational Safety and Health Administration, United States Department of Labor, published at 56 Fed. Reg. 64175 (December 6, 1991).

Respectfully submitted,

REED, SMITH SHAW &
McCLAY

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Dated: December 16, 1991

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT
Chicago, Illinois 60604

March 6, 1992

Nos. 91-3865, 92-1482 and 91-1483

By the Court:

AMERICAN DENTAL ASSOCIATION, HOME HEALTH SERVICES AND STAFFING ASSOCIATION, INCORPORATED, and AMERICAN HEALTH CARE ASSOCIATION,
Petitioners,

v.

LYNN MARTIN, SECRETARY OF LABOR AND OCCUPATIONAL SAFETY HEALTH REVIEW COMMISSION,
Respondents,

and

AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, AFL-CIO, and SERVICE EMPLOYEES INTERNATIONAL UNION, AFL-CIO,
Intervening-Respondents.

Petitions for Review of an Order of the
United States Department of Labor

ORDER

The court, on its own motion, orders that these appeals are CONSOLIDATED for purposes of briefing and disposition.

Briefing shall continue to be held in abeyance pursuant to the court's order of February 27, 1992.

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT
Chicago, Illinois 60604

February 10, 1993

Before

HON. RICHARD A. POSNER, *Circuit Judge*

No. 91-3865

AMERICAN DENTAL ASSOCIATION,
Petitioner,

v.

MARTIN, SECRETARY OF LABOR AND OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
Respondents,

and

AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, AFL-CIO, and SERVICE EMPLOYEES INTERNATIONAL UNION, AFL-CIO,
Intervening-Respondents.

Petition for Review of an Order of the
Occupational Safety and Health Administration

No. 92-1482

HOME HEALTH SERVICES AND STAFFING ASSOCIATION, INCORPORATED,
Petitioner,

v.

LYNN MARTIN, SECRETARY OF LABOR AND OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, UNITED STATES DEPARTMENT OF LABOR,
Respondents.

Petition for Review of an Order of the
Occupational Safety and Health Administration

This matter comes before the court for its consideration of the "MOTION FOR EXTENSION OF TIME TO FILE PETITION FOR REHEARING OR MOTION FOR CLARIFICATION" filed herein on February 9, 1993, by counsel for petitioner Home Health Services and Staffing Association, Incorporated. On consideration thereof,

IT IS ORDERED that said motion is GRANTED and the petition for rehearing of the Home Health Services and Staffing Association, Incorporated will be due by February 25, 1993.

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT
Chicago, Illinois 60604

May 27, 1993

Before

HON. RICHARD A. POSNER, Circuit Judge

HON. JOHN L. COFFEY, Circuit Judge

HON. FRANK H. EASTERBROOK, Circuit Judge

Nos. 91-3865, 92-1482

AMERICAN DENTAL ASSOCIATION and
HOME HEALTH SERVICES AND
STAFFING ASSOCIATION, INC.,
Petitioners,

v.

LYNN MARTIN, SECRETARY OF LABOR AND OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, UNITED STATES DEPARTMENT OF LABOR,
Respondents,

AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, AFL-CIO, and SERVICE EMPLOYEES INTERNATIONAL UNION, AFL-CIO,
Intervening-Respondents.

Petitions for Review of an Order of the
Occupational Safety and Health Administration

ORDER

On February 25, 1993, petitioner Home Health Services and Staffing Association, Inc. filed a petition for rehearing with a suggestion for rehearing en banc. All the judges on the original panel have voted to deny the petition, and none of the active judges has requested a vote on the suggestion for rehearing en banc. The petition is therefore DENIED.

EXCERPTS FROM THE PREAMBLE TO THE FINAL RULE ON OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS

56 Federal Register at 64,028-029

TABLE V-6.—HBV RISK ATTRIBUTABLE TO OCCUPATIONAL EXPOSURE FOR HEALTHCARE WORKERS EXPOSED TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIAL [a, b]

	Annual risk [c]	Lifetime occupational risk[d]
HBV Infections	1.928-2.671	83.18-113.40
Clinical Illness (25%)	0.482-0.668	21.46-29.61
Hospitalized (5%)	0.096-0.134	4.33-5.99
HBV Carrier (5%-10%)	0.096-0.267	4.33-11.95
Chronic HBV (25% Carriers)	0.024-0.067	1.08-3.00
Fulminant Death (.125%)	0.002-0.003	0.11-0.15
Death—Cirrhosis (1.7%)	0.033-0.045	1.47-2.04
Death—PHC (0.4%)	0.008-0.011	0.35-0.48
All Deaths (2.225%)	0.043-0.059	1.93-2.67

[a] Risks are expressed as the number of events per 1,000 exposed healthcare workers who lack immunity.

[b] The risk attributable to occupational exposure is the difference between the annual risk faced by exposed workers and the annual risk faced by the adult population, both given in Table V-5.

[c] Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.

[d] Assume 45 years of occupational exposure and is calculated as $[1-(1-p)^{45}]$, where p is the annual risk divided by 1,000. Assumes p is constant through time.

56 Federal Register at 64,029

To estimate the remaining occupational risk after vaccination, OSHA will assume a 96% vaccine efficacy rate instead of 92.7%, which is Merck's estimate of vaccine efficacy adjusted for the age distribution of those covered by this standard.

56 Federal Register at 64,034

Although it is not possible to quantify the risk of HIV infection in healthcare or other workers with occupational exposure to blood or other potentially infectious material or with direct exposure to the virus itself, the data show that a risk does exist. As the number of people with HIV-associated illnesses increases, the probability that workers exposed to blood or other potentially infectious material will also be exposed to HIV also increases. Given needlestick exposure to HIV-infected blood, the risk of seroconversion is estimated to be between 3.5 to 4.7 per 1000 exposures. For research and production laboratory workers with occupational exposure to high concentrations of the virus, the risk of seroconversion is estimated to be 4.8 per 1000 person-years. Over a 45 year working lifetime, the risk would be 195 per 1000 exposed workers. By reducing the risk of exposure to blood and other potentially infectious material and by strictly adhering to biosafety procedures in handling the virus in laboratories, the risk of HIV infection can be reduced.

As described in the health effects discussions, there are other bloodborne pathogens, such as syphilis and malaria, which are present in blood during certain phases of infection. During these phases, the blood of infected individuals poses a risk to exposed workers. Although the risk of these infections has not been quantified, it does exist and will be minimized or eliminated by preventing occupational exposure to blood.

56 Federal Register at 64,036

After thoroughly considering the magnitude of the risk as shown by the quantitative and qualitative data, OSHA concludes that the risk of death and material impairment of health resulting from acute and chronic HBV infection is significant, that HBV presents a significant risk of both unvaccinated employees and employees who have been vaccinated but have not developed immunity. Moreover, because HBV is not the only bloodborne pathogen capable of causing disease, all employees who are exposed to blood and other potentially infectious materials, whether they are HB-vaccinated or not, may be at risk of infection.

At this time, OSHA believes that there are not sufficient data on HIV to quantify the occupational risk of infection. Nevertheless, the epidemiological data on HIV provide strong qualitative evidence that HIV can be transmitted in the workplace and serve to further illustrate risk remaining after the major protection measure of HBV vaccination is implemented. Individuals who have a needlestick exposure to blood from an HIV infected individual have a 3 to 4 per 1,000 risk of developing an HIV infection.

56 Federal Register at 64,088

Thus, OSHA has also required the hepatitis B vaccine to be offered to occupationally exposed employees free of charge. Three alternatives to this requirement were considered. First, OSHA considered limiting the population of workers offered the hepatitis B vaccine to that portion of the affected workforce occupationally exposed an average of once a month or more. OSHA's second alternative was to require all employers to offer the vaccine, free of charge, to occupationally exposed workers, regardless of frequency of exposure. A third alternative would be to mandate the vaccination of all exposed employees. However, this alternative would not protect workers from other bloodborne pathogens.

56 Federal Register at 64,155

After reviewing the record, and considering all the above comments OSHA concludes that a voluntary vaccination program is the best approach to foster greater employee cooperation and trust in the system. While the Agency may have the legal auhority to require vaccinations as part of the standard, it recognizes that voluntary participation by employees enhances compliance while respecting individuals' beliefs and rights to privacy. Accordingly, OSHA has chosen to require employers to offer Hepatitis B vaccination, but to make participation in the program voluntary.

EXCERPTS FROM TRANSCRIPTS OF OSHA RULEMAKING HEARINGS

Dr. Enid A. Neidle, Assistant Executive Director of the ADA Division of Scientific Affairs (Tr. 9/21/89) p. 158 (Record Ex. 332X)

The Association also recommends the determination of when safety glasses or goggles should be used, should be left to the professional judgment of the dentist. Although there may be some spraying of saliva mixed with blood in routine dental procedures, the amounts involved are small and it is rare to have any blood or saliva spray into the dental healthcare worker's eyes during routine procedures.

Dr. Henry Finger, President Elect of the Academy of General Dentistry (Tr. 9/22/89) pp. 8-9, 28 (Record Ex. 339X)

Fluid proof gowns, head coverings and shoe coverings should never be needed in general dental procedures. Work practices such as proper patient positioning, use of a rubber dam and high speed suction will effectively minimize spraying and splattering. The standards will permit flexibility in replacing or augmenting the use of some of this personal protective equipment with work practice controls, according to the dentist's professional judgment.

The way the proposed rule is currently written, it will require fluid resisting clothing and surgical caps or hoods be worn if there is a potential for splashing or splattering of blood or other potentially infections materials. In virtually any dental procedure, splashing is possible, but often is not probable.

The standard should require the use of these protective items only when splashing or splattering is probable or likely. In my twenty-five years of practicing dentistry, I have never splattered blood on my shoes or on my hair.

* * * *

MR. ANDREI: You also testified that risk of exposure can be minimized through engineering controls, among other measures. Could you please give us some examples of engineering controls presently available or under development which would reduce risk of exposure in dentistry?

DR. FINGER: Well, some of the engineering controls are just simply the way you treat the patient. If you place the patient back in a supine position where they're laying down—which we treat most patients in a sit-down position—The potential for splashing up is much less.

Secondly, by using a high speed evacuator which the assistant uses to aspirate, most of the splashing and the splattering is aspirated rather than splashing out of the mouth. The rubber dam is another way which we discussed earlier.

Dr. Chauncey Cross, ADA and U.S. Practicing Dentists
Tr. (10/19/89) p. 427 (Record Ex. 339X)

We look at these subjective side shields on the glasses, they may be of benefits, but I think that many of us are not looking at the way dentistry is practiced today, and the splattering of blood in the room. Most dentists work today with a chair-side assistant who has a high volume aspirator. She sits besides the patient, the dentist usually sits in back or beside the patient, the patient's head is tilted forward and up. The assistant should actually be aspirating all of that debris out of the side of the mouth. There is very little spray in the room. We can say that—can take films and show different kinds of sprays, but I think if you look around the room, you don't see debris around the room. Anyone who has been in a dental office certainly doesn't see splatters all over the place when they finish their appointment. Side shields on the glasses would certainly impede lateral vision, peripheral vision. It would make a sometimes very difficult job even more difficult.

Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures

[40 MMWR 1, 5-6 (1991)]

This document has been developed by the Centers for Disease Control (CDC) to update recommendations for prevention of transmission of human immunodeficiency virus (HIV) and hepatitis B virus (HBV) in the health-care setting. Current data suggest that the risk for such transmission from a health-care worker (HCW) to a patient during an invasive procedure is small; a precise assessment of the risk is not yet available. This document contains recommendations to provide guidance for prevention of HIV and HBV transmission during those invasive procedures that are considered exposure-prone.

* * * *

RECOMMENDATIONS

Investigations of HIV and HBV transmission from HCWs to patients indicate that when HCWs adhere to recommended infection-control procedures, the risk of transmitting HBV from an infected HCW to a patient is small, and the risk of transmitting HIV is likely to be even smaller. However, the likelihood of exposure of the patient to an HCW's blood is greater for certain procedures designated as exposure-prone. To minimize the risk of HIV or HBV transmission, the following measures are recommended:

- All HCWs should adhere to universal precautions, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments. HCWs who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment and devices used in performing invasive procedures until

the condition resolves. HCWs should also comply with current guidelines for disinfection and sterilization of reusable devices used in invasive procedures.

- Currently available data provide no basis for recommendations to restrict the practice of HCWs infected with HIV or HBV who perform invasive procedures not identified as exposure-prone, provided the infected HCWs practice recommended surgical or dental technique and comply with universal precautions and current recommendations for sterilization/disinfection.
- Exposure-prone procedures should be identified by medical/surgical/dental organizations and institutions at which the procedures are performed.
- HCWs who perform exposure-prone procedures should know their HIV antibody status. HCWs who perform exposure-prone procedures and who do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status and, if that is positive, should also know their HBeAg status.
- HCWs who are infected with HIV or HBV (and are HBeAg positive) should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures.* Such circum-

---

* The review panel should include experts who represent a balanced perspective. Such experts might include all of the following: a) the HCW's personal physician(s), b) an infectious disease specialist with expertise in the epidemiology of HIV and HBV transmission, c) a health professional with expertise in the procedures performed by the HCW, and d) state or local public health official(s). If the HCW's practice is institutionally based, the expert review panel might also include a member of the infection-control committee, preferably a hospital epidemiologist. HCWs who

stances would include notifying prospective patients of the HCW's seropositivity before they undergo exposure-prone invasive procedures.

- Mandatory testing of HCWs for HIV antibody, HBsAg, or HBeAg is not recommended. The current assessment of the risk that infected HCWs will transmit HIV or HBV to patients during exposure-prone procedures does not support the diversion of resources that would be required to implement mandatory testing programs. Compliance by HCWs with recommendations can be increased through education, training, and appropriate confidentiality safeguards.

---

perform exposure-prone procedures outside the hospital/institutional setting should seek advice from appropriate state and local public health officials regarding the review process. Panels must recognize the importance of confidentiality and the privacy rights of infected HCWs.

Recommendations for Prevention of HIV Transmission in Health-Care Settings

[36 MMWR 3S, 5S, 11S-12S (1987)]

* * * *

Universal Precautions

Since medical history and examination cannot reliably identify all patients infected with HIV or other blood-borne pathogens, blood and body-fluid precautions should be consistently used for *all* patients. This approach, previously recommended by CDC (*3, 4*), and referred to as "universal blood and body-fluid precautions" or "universal precautions," should be used in the care of *all* patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown (*20*).

* * * *

Laundry

Although soiled linen has been identified as a source of large numbers of certain pathogenic microorganisms, the risk of actual disease transmission is negligible. Rather than rigid procedures and specifications, hygienic and common-sense storage and processing of clean and soiled linen are recommended (*26*). Soiled linen should be handled as little as possible and with minimum agitation to prevent gross microbial contamination of the air and of persons handling the linen. All soiled linen should be bagged at the location where it was used; it should not be sorted or rinsed in patient-care areas. Linen soiled with blood or body fluids should be placed and transported in bags that prevent leakage. If hot water is used, linen should be washed with detergent in water at least 71 C (160 F) for 25 minutes. If low-temperature ($\leq$70 C [158 F]) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration should be used.

Perspectives in Disease Prevention and Health Promotion

Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings

[37 MMWR 377, 379 (1988)]

* * * *

Universal precautions do not apply to saliva. General infection control practices already in existence—including the use of gloves for digital examination of mucous membranes and endotracheal suctioning, and handwashing after exposure to saliva—should further minimize the minute risk, if any, for salivary transmission of HIV and HBV (*1, 25*). Gloves need not be worn when feeding patients and when wiping saliva from skin.

Special precautions, however, are recommended for dentistry (*1*). Occupationally acquired infection with HBV in dental workers has been documented (*4*), and two possible cases of occupationally acquired HIV infection involving dentists have been reported (*5, 26*). During dental procedures, contamination of saliva with blood is predictable, trauma to health-care workers' hands is common, and blood spattering may occur. Infection control precautions for dentistry minimize the potential for nonintact skin and mucous membrane contact of dental health-care workers to blood-contaminated saliva of patients. In addition, the use of gloves for oral examinations and treatment in the dental setting may also protect the patient's oral mucous membranes from exposures to blood, which may occur from breaks in the skin of dental workers' hands.

(2)

No. 93-7

FILED
AUG 30 1993
OFFICE OF THE CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1993

AMERICAN DENTAL ASSOCIATION, PETITIONER

v.

ROBERT B. REICH, SECRETARY OF LABOR, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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31 pp

QUESTIONS PRESENTED

1. Whether OSHA was justified in including dental care workers in its finding that workers in the health care industry face a significant risk of harm from exposure to bloodborne pathogens.

2. Whether OSHA improperly failed to adopt a more cost-effective alternative to the bloodborne pathogens standard.

3. Whether the court of appeals misapprehended or grossly misapplied the substantial evidence standard of review.

TABLE OF CONTENTS

	Page
Opinion below	1
Jurisdiction	1
Statement	1
Argument	12
Conclusion	26

TABLE OF AUTHORITIES

Cases:

AFL-CIO v. *Marshall*, 617 F.2d 636 (D.C. Cir. 1979), aff'd in part and vacated in part *sub nom. American Textile Mfrs. Inst., Inc.* v. *Donovan*, 452 U.S. 490 (1981)	16
AFL-CIO v. *OSHA*, 965 F.2d 962 (11th Cir. 1992)	17
American Textile Mfrs. Inst., Inc. v. *Donovan*, 452 U.S. 490 (1981)	5, 13, 19, 20
Associated Builders & Contractors, Inc. v. *Brock*, 862 F.2d 63 (3d Cir. 1988), cert. denied, 490 U.S. 1064, 1065 (1989), and 494 U.S. 1003 (1990)	16
Atlas Roofing Co. v. *OSHRC*, 430 U.S. 442 (1977)	13
Building & Constr. Trades Dep't, AFL-CIO v. *Brock*, 838 F.2d 1258 (D.C. Cir. 1988)	19
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Gade v. *National Solid Wastes Management Ass'n*, 112 S. Ct. 2374 (1992)	23
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International Union, UAW v. *OSHA*, 938 F.2d 1310 (D.C. Cir. 1991)	17, 18
International Union, UAW v. *Pendergrass*, 878 F.2d 389 (D.C. Cir. 1989)	21
National Grain & Feed Ass'n v. *OSHA*, 866 F.2d 717 (5th Cir. 1989)	21

Cases—Continued: Page

Public Citizen Health Research Group v. *Tyson*, 796 F.2d 1479 (D.C. Cir. 1986) 21
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Usery v. *Marquette Cement Mfg. Co.*, 568 F.2d 902 (2d Cir. 1977) 24

Statutes, regulations and rule:

Department of Labor Appropriations Act, 1992, Pub. L. No. 102-170, Tit. I, 105 Stat. 1107 ..... 8, 25
§ 100, 105 Stat. 1113-1114 8
Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*:
§ 2(b), 29 U.S.C. 651(b) 13
§ 3(8), 29 U.S.C. 652(8) 19
§ 5(a)(1), 29 U.S.C. 654(a)(1) 7, 22
§ 6(a), 29 U.S.C. 655(a) 13
§ 6(b), 29 U.S.C. 655(b) 13
§ 6(b)(5), 29 U.S.C. 655(b)(5) 13, 14, 16, 19, 25
§ 6(f), 29 U.S.C. 655(f) 9
§ 6(g), 29 U.S.C. 655(g) 16
Treasury, Postal Service and General Government Appropriations Act, 1992, Pub. L. No. 102-141, 105 Stat. 834 24
§ 633, 105 Stat. 876 24-25
29 C.F.R.:
Section 1910.1030 2
Section 1910.1030(a) 3
Section 1910.1030(b) 2, 3
Section 1910.1030(b)(1) 3
Section 1910.1030(d)(2)(vi) 4
Section 1910.1030(d)(2)(viii) 4
Section 1910.1030(d)(3)(i) 4
Section 1910.1030(d)(4) 4

Regulations and rule—Continued: Page

Section 1910.1030(f)(1) 4
Section 1910.1030(f)(3)(iii)-(vi) 4
Sup. Ct. R. 14.1(a) 22

Miscellaneous:

56 Fed. Reg. (1991):
pp. 64,004-64,182 2
p. 64,006 3
p. 64,007 ..... 3, 7, 22, 23
p. 64,008 2
p. 64,009 2
p. 64,010 ..... 2, 3
p. 64,012 3
p. 64,013 3
p. 64,014 6
p. 64,016 3
p. 64,017 3
pp. 64,022-64,023 3
p. 64,024 5
pp. 64,028-64,029 5
p. 64,030 6
p. 64,034 6
p. 64,035 5
p. 64,036 ..... 6, 7
p. 64,037 ..... 6, 8
p. 64,038 ..... 7, 22
p. 64,056 5
p. 64,080 8
p. 64,087 8
p. 64,088 8
p. 64,092 7
p. 64,103 ..... 3, 7
pp. 64,154-64,155 8
H.R. Rep. No. 1291, 91st Cong., 2d Sess. (1970) 24
Infection control recommendations for the dental office and the dental laboratory, 116 J. A.D.A. 241 (1988) 7
S. Rep. No. 1282, 91st Cong., 2d Sess. (1970) 24

In the Supreme Court of the United States

OCTOBER TERM, 1993

No. 93-7

AMERICAN DENTAL ASSOCIATION, PETITIONER

v.

ROBERT B. REICH, SECRETARY OF LABOR, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-52a) is reported at 984 F.2d 823.

JURISDICTION

The judgment of the court of appeals was entered on January 28, 1993. A petition for rehearing was denied on May 27, 1993. The petition for a writ of certiorari was filed on June 28, 1993. This Court's jurisdiction is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. On December 6, 1991, the Occupational Safety and Health Administration (OSHA) issued a final

standard governing occupational exposure to bloodborne pathogens. Pet. App. 2a; 29 C.F.R. 1910.1030 (see 56 Fed. Reg. 64,004-64,182 (1991)). Petitioner has challenged the rule insofar as it applies to dental care employers.

a. The bloodborne pathogens standard was designed to eliminate or minimize grave health risks from occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other bloodborne pathogens. Pet. App. 2a; 56 Fed. Reg. 64,004-64,182.[1] A person infected with HBV has a 1 in 3 chance of contracting acute hepatitis, a serious and (in about 1% of infections) fatal liver disease. Pet. App. 3a; 56 Fed. Reg. 64,009. In addition, a significant percentage (6-10%) of individuals infected with HBV become chronic HBV carriers, who are capable of passing the infection on to others and are subject to a high risk of developing serious and potentially fatal diseases, including hepatitis, cirrhosis of the liver and primary liver cancer. Pet. App. 3a; 56 Fed. Reg. 64,009. HBV can be transmitted in the workplace through blood-to-blood contact (as when a health care employee suffers a puncture wound or cut contaminated with an infected individual's blood) or through the virus's contact with the mucous membranes in an employee's eyes or mouth. Pet. App. 2a, 3a; 56 Fed. Reg. 64,010. HBV can survive for at least a week at room temperature and infection has been shown to result from contact with

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[1] A bloodborne pathogen is a disease-causing microorganism found in blood that can be transmitted from an infected individual to others through exposure to the infected person's blood or other body fluids. See 29 C.F.R. 1910.1030(b); 56 Fed. Reg. 64,008.

environmental surfaces. Pet. App. 3a; 56 Fed. Reg. 64,010. A vaccination exists for HBV that produces antibodies in, and hence is effective for, 85% to 97% of persons to whom it is administered. Pet. App. 3a; 56 Fed. Reg. 64,012.

Infection with HIV leads to acquired immune deficiency syndrome (AIDS), a disease that to date has proven invariably fatal. 56 Fed. Reg. 64,006. Although HIV is less easily transmitted than HBV, HIV can also be spread by the type of blood-to-blood contact that may occur in a health care setting, as in a needlestick, or when blood contacts an employee's non-intact skin or mucous membranes. Pet. App. 2a-3a; 56 Fed. Reg. 64,016, 64,017.[2]

b. OSHA's bloodborne pathogens standard applies to employees who may reasonably anticipate skin, eye, or mucous membrane contact with blood in the performance of their duties. 29 C.F.R. 1910.1030(a) and (b). Because saliva often becomes contaminated with blood during dental procedures, 56 Fed. Reg. 64,103, the standard includes "saliva in dental procedures" as a potentially infectious material. 29 C.F.R. 1910.1030 (b)(1). The standard is modeled to a significant degree on guidelines issued by the Centers for Disease Control and Prevention (CDC) as they existed at the time of the rule's promulgation, although the standard is more detailed and contains additional requirements. 56 Fed. Reg. 64,007. Like the CDC guidelines, the standard is based on the principle of "universal precautions," which means

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[2] Other diseases that can be transmitted through bloodborne pathogens include hepatitis C, syphilis, and malaria. 56 Fed. Reg. 64,013, 64,022-64,023.

that precautions apply to contact with blood and other potentially infectious material of every patient, not just those known or believed to be carriers of HBV or HIV. Pet. App. 3a.[3]

The precautions required by the standard include: engineering controls (such as the provision of appropriate containers for disposing of contaminated sharp instruments, like needles), 29 C.F.R. 1910.1030 (d)(2)(viii); work practice controls (such as the requirement that employees wash their hands and other skin immediately after contact with blood or other potentially infectious materials), *id.* § 1910.1030 (d)(2)(vi); requirements for personal protective equipment such as gloves and gowns, *id.* § 1910.1030(d)(3)(i); and housekeeping requirements covering the cleaning of contaminated surfaces and laundry and the disposal of contaminated waste, *id.* § 1910.1030(d)(4). See Pet. App. 3a-4a. In addition, the standard requires employers to offer employees, at the employer's expense, the opportunity to receive a Hepatitis B vaccine. 29 C.F.R. 1910.1030(f)(1); Pet. App. 4a. Also, employees involved in an "exposure incident," such as a needlestick, must be offered (at no employee expense) confidential bloodtesting, medical evaluation and counseling, and, if warranted, post-exposure prophylaxis. 29 C.F.R. 1910.1030(f)(3)(iii)-(vi).

c. In promulgating the standard, OSHA determined that bloodborne pathogens posed a significant risk of material health impairment to employees and

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[3] The CDC guidelines, while generally exempting saliva from the list of body fluids to which universal precautions apply, recommended "special precautions" for dental workers exposed to saliva from patients. See Pet. App. 8a.

that the standard was reasonably necessary or appropriate to eliminate or substantially reduce that risk. See generally *American Textile Mfrs. Inst., Inc.* v. *Donovan*, 452 U.S. 490, 506 (1981) (*Cotton Dust*); *Industrial Union Dep't, AFL-CIO* v. *American Petroleum Inst.*, 448 U.S. 607, 614-615, 639, 642-643 (1980) (plurality opinion) (*Benzene*). The agency specifically found that a number of epidemiological studies demonstrated an increased prevalence of Hepatitis B markers in the blood of health care workers with exposure to blood, 56 Fed. Reg. 64,024; that it is the exposure to blood that places health care employees at risk and not some other factor, *ibid.*; and that because it takes only one exposure to infected blood to transmit the virus, any worker with exposure to blood is at risk of infection, *id.* at 64,056.

In finding that the risk of HBV is significant, the agency undertook a quantitative assessment of the risk to health care workers. Based on data gathered by the CDC, OSHA calculated that over a 45-year working lifetime, 83 to 113 of every 1000 non-immune health care workers would suffer HBV infection, 21 to 30 of these would develop clinical illness, 4 to 6 would be hospitalized, and 2 to 3 would die. Pet. App. 90a; 56 Fed. Reg. 64,028-64,029, 64,035. Occupationally acquired HBV kills about 200 health care workers in the United States annually. Pet. App. 3a.

OSHA also determined that, although vaccination greatly reduces the risk of HBV infection, a significant risk from HBV infection would exist even if all workers received an HBV vaccination. Assuming universal inoculation and a 96% vaccine efficacy rate, OSHA found that 3 to 5 of every 1000 health care workers still would be infected by HBV in a working

lifetime, and that one of those would contract a clinical illness. 56 Fed. Reg. 64,030, 64,037. OSHA further noted, however, that voluntary vaccination programs had not achieved a 100% acceptance rate, and based on data concerning the numbers of employees vaccinated under voluntary programs, the agency determined that the acceptance rate would average only 50% among all of the workers within the scope of the standard. *Id.* at 64,030.

Although the agency issued more detailed findings on HBV than on HIV, OSHA also concluded that available data showed that a risk of occupational HIV transmission exists for health care workers.[4] The agency determined that the data did not permit a quantitative assessment of that risk, 56 Fed. Reg. 64,034, but the "strong qualitative evidence that HIV can be transmitted in the workplace * * * serve[s] to * * * illustrate [the] risk remaining after the major protection measure of HBV vaccination is implemented." *Id.* at 64,036.

OSHA further determined that its assessment of significant risk of material impairment of worker health justified imposition of a standard based on a worker's occupational exposure to blood, without regard to the worker's particular occupation or workplace setting. OSHA noted that "[h]aving specific quantitative data for non-health care workers and for particular occupations and locations would add more precision to the quantitative risk assessment, but that level of detail is not possible, given the data

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[4] As of the close of the rulemaking record in 1990, approximately 24 cases of occupational HIV infection of health care workers in the United States had been documented. 56 Fed. Reg. 64,014.

available in the [rulemaking] record, nor necessary to a finding of significant risk, especially when the risk of infection is based upon occupational exposure to blood or other potentially infectious materials." 56 Fed. Reg. 64,036.

Nevertheless, OSHA gave specific consideration to the dental sector of the health care industry. Pet. App. 7a-9a. The agency observed that "[d]entists, dental hygienists, dental assistants and dental laboratory technicians are continually exposed to blood and bloody saliva during almost all dental procedures"[5] and that the record contained many references to occupational Hepatitis B infections in dental health professionals. 56 Fed. Reg. 64,092.[6]

d. OSHA also discussed regulatory alternatives. In particular, it explained why a specific standard would be advantageous to enforcement of some protective measures against bloodborne pathogens under the Occupational Safety and Health (OSH) Act's "general duty" clause (29 U.S.C. 654(a)(1)). See 56 Fed. Reg. 64,007, 64,038. OSHA also concluded that

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[5] See also 56 Fed. Reg. 64,103 (quoting CDC guidelines stating that "[d]uring dental procedures, contamination of saliva with blood is predictable, trauma to health-care workers' hands is common, and blood spattering may occur").

[6] See generally 56 Fed. Reg. 64,092 (noting that many dentists remained unvaccinated against HBV and citing an article from the Journal of the American Dental Association stating that "[i]n the late 1970s, it became clear that dentists are at a risk three times greater than that of the general population for hepatitis B"). See also *Infection control recommendations for the dental office and the dental laboratory*, 116 J. A.D.A. 241, 241 (1988) ("Dental health care personnel have long been recognized to be at high risk for acquiring hepatitis B through contact with patients.").

voluntary adherence to "non-enforceable" CDC guidelines calling for universal precautions would "not result in an adequate level of protection to the nation's health care and public safety workforce." *Id.* at 64,087. OSHA also explained that it declined to impose a mandatory HBV vaccination program because not all workers are willing to be vaccinated because of medical, religious, or privacy reasons. *Id.* at 64,037, 64,088, 64,154-64,155. Furthermore, as noted, OSHA determined that a significant risk of HBV remained even with a universal vaccine and that the vaccine would not protect against other bloodborne pathogens, such as HIV. Therefore, the other requirements of the standard would be needed even if all workers were vaccinated. *Id.* at 64,037.[7]

2. On November 26, 1991, after the agency closed the rulemaking record but before the standard was promulgated, Congress enacted the Department of Labor Appropriations Act, 1992, Pub. L. No. 102-170, Tit. I, 105 Stat. 1107. That law directed OSHA to publish by December 1, 1991, a final rule on bloodborne pathogens, based on the agency's May 30, 1989, proposed standard. The statute further provided that, in the event the agency did not act by that date, the proposed standard would take effect until the agency issued a final rule. *Id.* § 100, 105 Stat. 1113-1114.

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[7] OSHA conducted an extensive analysis of the feasibility of the bloodborne pathogens standard. In particular, OSHA concluded that the expected compliance costs for a dentist's office will amount to less than one percent of total income and that this impact would not cause undue harm in this sector of the health care industry. 56 Fed. Reg. 64,080. Petitioner has not sought review of the court of appeals' ruling upholding this feasibility determination.

OSHA issued the bloodborne pathogens standard on December 6, 1991.

3. Pursuant to Section 6(f) of the OSH Act, 29 U.S.C. 655(f), petitioner sought review in the court of appeals of the standard as applied to dental health care settings.[8] The court of appeals rejected petitioner's challenge.

a. In affirming the agency's findings that the measures imposed by the standard would reduce a significant workplace risk to human health, the court of appeals concluded that "OSHA's evaluation of the effects of the rule, relying as it does on the undoubted expertise of the Centers for Disease Control, cannot seriously be faulted." Pet. App. 5a. The court noted OSHA's findings that the rule would eliminate between 113 and 129 annual deaths of health care workers from HBV, and between 187 and 197 deaths if individuals infected by health care workers were included. *Id.* at 4a-5a. And it noted that, although most of those deaths could be avoided by the HBV vaccine, "the vaccine is not a hundred percent effective and, more important, * * * many health care workers refuse to be vaccinated." *Id.* at 5a. The court thus concluded that the additional requirements of the rule, beyond the voluntary vaccination program, would have a "positive effect * * * on [HBV]" as well

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[8] As the court of appeals noted, most employers in the health care industry accepted OSHA's rule. Pet. App. 2a. In addition to petitioner, one other employer group—representing medical personnel employers (who supply health care workers on a temporary basis to hospitals and nursing homes) and home health employers (who supply such workers to patients at home)—challenged the rule. *Ibid.*

as on prevention of HIV, for which there is no vaccine. *Ibid.*

The court rejected petitioner's assertions that OSHA improperly "lumped [dental care employers] in with" medical professionals who are far more exposed to patients' blood. Pet. App. 7a. The court noted that OSHA "gave separate consideration to every point raised before it by the dental association." *Ibid.* Thus, OSHA pointed out that the saliva of dental patients frequently contains blood—even in such routine procedures as teeth-cleaning—and that it is possible that even a small quantity of blood can sometimes be infective. *Id.* at 7a-8a. That conclusion was supported as well, the court held, by CDC guidelines recommending "special precautions" for saliva in dental procedures, as opposed to saliva in other patient care contexts for which precautions against bloodborne pathogens are not advised. *Id.* at 8a.

In rejecting petitioner's assertion that OSHA impermissibly failed to disaggregate the risk "industry by industry," the court acknowledged that "OSHA cannot impose onerous requirements on an industry that does not pose substantial hazards to the safety or health of its workers merely because the industry is a part of some larger sector or grouping and the agency has decided to regulate at wholesale." Pet. App. 8a-9a. At the same time, however, the court observed that OSHA is not required to "proceed workplace by workplace, which in the case of bloodborne pathogens would require it to promulgate hundreds of thousands of separate rules." *Id.* at 9a. Here, the court concluded, the agency provided a rational explanation for its choice of a "happy

medium" between these two extremes. *Ibid.* Thus, OSHA explained that although the cost of compliance with the rule varies in readily determinable fashion from industry to industry,[9] the risk does not. Instead, that risk is associated with practices involving exposure to blood. And, the court noted, although the risk of blood spatters and needlesticks is greater in some medical procedures than others, a dental worker is as likely to be spattered by blood as many workers in doctors' offices or hospitals. The court thus concluded that "[t]he idea behind requiring universal precautions for health care workers is to protect those workers in any situation in which there is a nontrivial risk of physical contact with a patient's blood, and these situations arise in dentists' offices as well as in doctors' offices and hospitals." *Ibid.*[10]

b. Judge Coffey dissented in part. Although he acknowledged (Pet. App. 21a) that OSHA had power to regulate workplace safety, he suggested that Con-

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[9] The court specifically rejected petitioner's argument that the agency had improperly found the rule to be economically feasible for the dental sector of the health care industry. Pet. App. 12a. Noting that since, "[a]nnualized, [the costs of compliance] are estimated to be equal to less than one-third of one percent of the [dental] industry's annual revenues," such costs could "hardly be thought so great as to imperil dentistry." *Ibid.*

[10] Although it also upheld (Pet. App. 10a-12a) the specific components of the standard against petitioner's other challenges, the court of appeals vacated portions of the standard insofar as it applied to the medical personnel and home health care industries. The court held that OSHA had not adequately addressed feasibility concerns arising from the fact that employers in those industries do not control the worksites at which their employees work. *Id.* at 13a-16a.

gress should "address the question * * * whether OSHA [in addition to the CDC] is the proper agency to regulate health care." *Id.* at 19a; see also *id.* at 21a, 27a-28a, 30a-31a, 41a-44a, 48a n.27, 50a-52a.

Judge Coffey also concluded that OSHA improperly aggregated various sectors in the health care industry to arrive at an artificial risk level applicable to the industry as a whole. Pet. App. 21a-26a. Furthermore, Judge Coffey concluded that, in determining whether significant risks will be eliminated by the standard, the agency did not properly take into account the "current state of regulation," including "the CDC Guidelines adopted by the states," other individual state and professional regulations, and the increased use of HBV vaccinations in the dental profession. The failure to do so, he concluded, rendered the agency's rule arbitrary and capricious. *Id.* at 29a-30a. Judge Coffey also criticized the agency for failing to require mandatory vaccinations, which would in his view render the additional requirements of the standard unnecessary to protect against HBV. *Id.* at 32a-33a.[11]

ARGUMENT

The decision of the court of appeals upholding the application of OSHA's bloodborne pathogens standard to dental care employers is correct and does not conflict with any decision of this Court or any court of appeals. Accordingly, review by this Court is not warranted.

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[11] Judge Coffey also concluded, contrary to the majority, see note 9, *supra*, that the agency's feasibility analysis was fatally flawed because of its failure to take into account certain costs. Pet. App. 46a-50a.

1. Congress enacted the OSH Act "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources," 29 U.S.C. 651(b), and to that end gave the Secretary of Labor the authority to issue mandatory occupational safety and health standards. 29 U.S.C. 655(a) and (b). See also *Atlas Roofing Co.* v. *OSHRC*, 430 U.S. 442, 444-445 (1977). In promulgating a standard which deals with "toxic materials or harmful physical agents," Congress directed the Secretary to adopt the "standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." 29 U.S.C. 655(b)(5).

Under this Court's decisions in *American Textile Mfrs. Inst., Inc.* v. *Donovan*, 452 U.S. 490, 506 (1981) (*Cotton Dust*), and *Industrial Union Dep't, AFL-CIO* v. *American Petroleum Inst.*, 448 U.S. 607, 614-615, 639, 642-643 (1980) (plurality opinion) (*Benzene*), before it may promulgate a standard, OSHA must determine that a substance poses a significant risk of material impairment to workers' health and that the standard is reasonably necessary or appropriate to eliminate or substantially reduce that risk. In requiring the Secretary to make a threshold finding of significant risk, however, this Court emphasized that the requirement is not a "mathematical straitjacket," that OSHA "is not required to support its finding * * * with anything approaching scientific certainty," and that a "reviewing court [is] to give OSHA some leeway where its findings must be made

on the frontiers of scientific knowledge." *Benzene*, 448 U.S. at 655-656 (plurality opinion). And, "so long as they are supported by a body of reputable scientific thought, the [a]gency is free to use conservative assumptions in interpreting the data * * *, risking error on the side of overprotection rather than underprotection." *Id.* at 656 (plurality opinion).

The court of appeals correctly ruled that OSHA made a significant risk finding that justified promulgation of the bloodborne pathogens standard generally and warranted application of the standard to workers in the dental care sector of the health care industry. OSHA found that unprotected exposure to blood creates a significant quantifiable risk of HBV infection, with the attendant potential for "material impairment of health or functional capacity," 29 U.S.C. 655(b)(5), including the risk of death. That finding was based on epidemiological studies demonstrating that health care workers become infected with HBV at a rate significantly greater than the general population. While not quantifiable, OSHA also determined that the available data demonstrate a risk of HIV transmission among health care workers. Finally, OSHA found that the risks from occupational contact with bloodborne pathogens could be substantially reduced by adoption of the standard. As the court of appeals concluded, those findings amply satisfy *Benzene*'s significant risk requirement.

Petitioner has not challenged the agency's findings for the health care industry generally. Rather, petitioner asserts (Pet. 12) that because OSHA failed to "disaggregate" the "24 [health care] industry sectors" and make a separate risk assessment for the dental care sector, the standard cannot reach

employees of dental employers. That contention, however, fundamentally misapprehends OSHA's significant risk assessment in this case. Based on the rulemaking record, including the epidemiological data on health care workers generally, OSHA found that any worker who has occupational exposure to blood faces a significant risk of HBV infection. The agency also determined, based on CDC findings, that saliva in dental procedures is a potentially infectious material because such saliva frequently contains blood.[12] The agency's detailed findings thus establish that dental care employees who in the course of their duties reasonably anticipate exposure to saliva face a significant risk of harm.

Petitioner's assertion (Pet. 12) that OSHA must in all circumstances disaggregate employer groupings by "industry" when making quantitative risk assessments is without support in the statute or case law. As the court of appeals recognized, OSHA must be provided leeway in determining the appropriate grouping of employers or employees that will yield a meaningful risk assessment in light of the standard at issue and the rulemaking record. Pet. App. 8a-9a. Thus, when OSHA finds a significant risk stemming from a work practice or work environment that is common to various industries,[13] it need not—

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[12] In its brief before the court of appeals, petitioner stated that 53.8% of annual patient visits to dentists involve exposure to blood, although that figure is reduced to 29.7% if periodontic, surgical, and restorative visits are excluded. Pet. C.A. Br. 10 & n.2.

[13] The statute makes clear that OSHA is authorized to adopt mandatory safety and health standards for particular

particularly in the absence of pertinent record evidence—quantify the risk for each affected industry.[14]

Benzene requires OSHA to find that exposure to a harmful substance is hazardous at a particular level, not that exposures at that level are hazardous in each industry in which exposure to that substance occurs. Similarly, in upholding OSHA's hazard communications standard, "a performance-oriented information disclosure standard covering thousands of chemical substances used in numerous industries," the Third Circuit rejected the argument that an industry-specific risk assessment was required, holding that "[f]or such a standard the significant risk requirement must of necessity be satisfied by a general finding concerning all potentially covered industries." *Associated Builders & Contractors, Inc.* v. *Brock*, 862 F.2d 63, 68 (3d Cir. 1988), certs. denied, 490 U.S. 1064, 1065 (1989), and 494 U.S. 1003 (1990). Indeed, a requirement that risk assessments must be industry-specific would "effectively cripple OSHA's

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"occupations" or "work environments" as well as for "particular industries." See 29 U.S.C. 655(g).

[14] Section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b)(5), requires OSHA to regulate workplace exposure to toxic substances and harmful physical agents based on the "best available evidence"—a task that allows it to "extrapolat[e] from limited data" and "fill gaps in knowledge with policy considerations." *AFL-CIO* v. *Marshall*, 617 F.2d 636, 651 (D.C. Cir. 1979), aff'd in part and vacated in part, *Cotton Dust*, 452 U.S. 490 (1981). See also *United Steelworkers* v. *Marshall*, 647 F.2d 1189, 1228 n.54 (D.C. Cir. 1980) (the standard of "best available evidence" permits OSHA "to act immediately to protect workers" even though contemporary science is unable to explain certain aspects of a problem), cert. denied, 453 U.S. 913 (1981).

performance of the duty imposed on it by 29 U.S.C. § 655(b)(5)," *ibid.*; it would also be unnecessary here, since all the covered employees engage in the same risk-creating work practice—exposure to blood.

In light of the agency's detailed significant risk findings for the bloodborne pathogens standard and its reasoned explanation for its coverage of the dental care sector of the health care industry, it is clear that the decision below does not conflict with the appellate decisions cited (Pet. 11) by petitioner. In *AFL-CIO* v. *OSHA*, 965 F.2d 962 (11th Cir. 1992), OSHA had promulgated a standard setting permissible exposure limits for 428 different air contaminants. In vacating that standard, the court of appeals concluded that "OSHA's discussions of individual substances generally contain no quantification or explanation of the risk from that individual substance." 965 F.2d at 975. The court of appeals thus believed that OSHA, in promulgating a multi-substance standard, had not adequately demonstrated significant risk for each substance. Here, by contrast, the agency provided extensive explanations, in both qualitative and quantitative terms, of the significant risks associated with occupational exposure to blood and other potentially infectious materials.

Nor does the decision below conflict with *International Union, UAW* v. *OSHA*, 938 F.2d 1310 (D.C. Cir. 1991). In that case, OSHA promulgated a "lockout/tagout" standard (requiring locking or tagging of energy sources for machinery during its service and maintenance in order to prevent the machinery's accidental activation) that applied to "virtually all equipment in almost all industries." 938 F.2d at 1312. The court of appeals ruled that OSHA

had inadequately explained its failure to disaggregate its significant risk findings by industry where there was record evidence of wide variations in injury rates among covered industries, including evidence that the injury rate in many of the covered industries was zero. Thus, the court directed OSHA on remand to explain how its aggregated approach conformed to the agency's interpretation of the OSH Act. *Id.* at 1322. In this case, the agency clearly explained its rationale for reliance on risk assessments derived from data on the health care industry generally, and gave specific reasons why such determinations should be applied to the dental sector. Indeed, there was evidence in the rulemaking record that dental care personnel are at a considerably higher risk of acquiring HBV infection than the general population. See note 6, *supra*.[15]

2. Petitioner contends (Pet. 13-14) that OSHA failed to determine whether the rule's requirements are cost-effective when compared to regulatory alternatives and that, had the agency done so, it would have mandated only a program of mandatory vaccination for HBV. That is because, in petitioner's view, mandatory vaccination would "virtually elim-

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[15] Petitioner's citation (Pet. 12) of decisions addressing OSHA's feasibility determinations does not support its argument. As the court below recognized (Pet. App. 8a), even where an OSHA standard focuses on a work practice or work environment condition that cuts across industries, OSHA's feasibility determination will often need to focus on an industry group. In fact, OSHA made a specific determination that the bloodborne pathogens standard would not be infeasible for dental employers in this case, and petitioner does not now challenge that determination.

inate" the risk of HBV, which petitioner characterizes as "the sole justification for the final rule." Pet. 14.

In *Cotton Dust*, this Court held that OSHA need not (and indeed may not) engage in cost-benefit analysis in deciding whether to promulgate a health standard under Section 6(b)(5) of the Act. Rather, in protecting workers from significant risks in the workplace, the agency must issue the rule that is most worker-protective within the limits of technological and economic feasibility, and need not "demonstrate that the reduction in risk of material health impairment is significant in light of the costs of attaining that reduction." 452 U.S. at 506. The Court in *Cotton Dust* reserved the further question whether Section 3(8) of the Act, 29 U.S.C. 652(8), which requires a standard to be "reasonably necessary or appropriate to provide safe or healthful employment," obliges OSHA in promulgating a Section 6(b)(5) standard to choose the least costly of two regulatory methods that "achieve the same reduction in health risk." 452 U.S. at 513 n.32.

In this case, OSHA considered various regulatory alternatives and determined that they were not equally effective in reducing the risk from bloodborne pathogens. Thus, it need not have considered the question of the cost-effectiveness of competing alternatives. Cf. *Building & Constr. Trades Dep't, AFL-CIO* v. *Brock*, 838 F.2d 1258, 1269 (D.C. Cir. 1988). OSHA rejected reliance on HBV vaccination alone because the HBV vaccination is not entirely effective, and because the additional requirements of the standard, such as workplace controls and personal protective equipment, would still be necessary to

reduce the significant risk of HBV infection that would remain after universal vaccination of workers. See pp. 5-6, 8, *supra*. Also, OSHA had two additional reasons for rejecting a mandatory vaccination scheme in favor of a voluntary vaccination scheme complemented by workplace controls: the workplace controls will provide substantial protection against infection by HIV and other bloodborne pathogens, and OSHA, as a matter of regulatory policy, did not wish to force workers unwilling to take the vaccine for medical, religious, or other reasons to submit to vaccinations. The agency thus acted well within the "zone of reasonableness" in adopting the bloodborne pathogen standard. *Forging Indus. Ass'n* v. *Secretary of Labor*, 773 F.2d 1436, 1443 (4th Cir. 1985) (en banc).

3. Petitioner errs in contending (Pet. 14-16) that further review is warranted because the court of appeals failed properly to review the record and determine whether OSHA's findings and determinations underlying the standard are supported by substantial evidence. This Court has stated that, because "the [OSH] Act places responsibility for determining substantial evidence questions in the courts of appeals," the Court "'will intervene only in what ought to be the rare instance when the [substantial evidence] standard appears to have been misapprehended or grossly misapplied' by the court below." *Cotton Dust*, 452 U.S. at 523, quoting *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 491 (1951). Petitioner falls far short of any showing that the court of appeals misapprehended or grossly misapplied the standard of review.

In support of its position (Pet. 14) that the court of appeals "took a hands off approach to the bloodborne pathogens rule" and neglected to conduct substantial evidence review, petitioner relies on statements by the court deferring to OSHA's expertise and its policy-making role and noting the limited role of the judiciary in reviewing such decisions. Such deference, however, is entirely consistent with the substantial evidence standard of review, and with the burden of proof outlined in this Court's decision in *Benzene*. See 448 U.S. at 656 (plurality opinion) ("OSHA is not required to support its finding * * * with anything approaching scientific certainty"; "a reviewing court [must] give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge"); see also *International Union, UAW* v. *Pendergrass*, 878 F.2d 389, 392 (D.C. Cir. 1989) ("our deference to the agency is at a peak for its choices among scientific predictions"); *National Grain & Feed Ass'n* v. *OSHA*, 866 F.2d 717, 729 (5th Cir. 1989); *Public Citizen Health Research Group* v. *Tyson*, 796 F.2d 1479, 1485 (D.C. Cir. 1986); *Forging Indus. Ass'n*, 773 F.2d at 1443.

Furthermore, petitioner's selective quotation (Pet. 15) from the court of appeals' opinion erroneously suggests that the panel majority found OSHA's fact-finding deficient, but nonetheless upheld the rule. In fact, the court of appeals explained why none of the perceived shortcomings altered the validity of the agency's conclusions. Rather than demonstrating that the court of appeals failed to review the record, those passages show that the court carefully reviewed the agency's findings. Although it detected some minor flaws, they did not draw into question the

action taken by the agency. Moreover, on the issues that are the focus of this petition—OSHA's application of its significant risk finding to dental care workers and its conclusion that a vaccination program by itself would have been insufficient—the court of appeals expressed no reservations whatsoever as to OSHA's fact-finding. Pet. App. 5a, 8a-10a.

4. Petitioner briefly argues (Pet. 10-11) that OSHA failed adequately to take the effects of preexisting regulation—including CDC guidelines and the OSH Act's general duty clause[16]—into account when it determined bloodborne pathogens posed a "significant risk" to workers in the health care industry.

The question whether OSHA must "consider existing controls before imposing costly and burdensome new requirements on industry" (Pet. 11) is not fairly included in the three questions presented in the petition, and further review to consider that question would therefore be unwarranted. See Sup. Ct. R. 14.1(a). Petitioner chose to present the questions whether OSHA committed error in failing to make a separate "significant risk" finding for the dental care sector, whether OSHA neglected an alternative regulation that allegedly would have been more cost-effective, and whether the court of appeals departed from accepted standards used in conducting "substantial evidence" review. See Pet i. The question whether OSHA erred in failing to assess the effects

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[16] The general duty clause requires each employer to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm." 29 U.S.C. 654(a)(1).

of pre-existing regulatory measures—none of which appear to apply distinctively to employment in dental care—does not appear to be fairly included within any of those questions.

In any event, petitioner's argument that OSHA erred is mistaken. Contrary to petitioner's contention, OSHA did specifically consider existing regulatory efforts to reduce risks from bloodborne pathogens. The agency explained that a specific bloodborne pathogen standard would promote reduction of risks beyond the reduction achieved by OSHA's enforcement under the general duty clause and beyond any level of voluntary compliance by employers with CDC guidelines. 56 Fed. Reg. 64,007, 64,038.[17]

Moreover, there is no support in the statute or case law for petitioner's contention that before OSHA may issue a specific standard it must demonstrate (let alone quantify) that case-by-case adjudication under the general duty clause has been insufficient to eliminate the risk. The statute provides OSHA with

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[17] Specifically, OSHA found that a standard would give more guidance to employers on the precautions needed to avoid bloodborne pathogens infection, would require more abatement methods than the general duty clause and the general industry standards, and would reduce the litigation burden on OSHA and employers. Moreover, the 23 States and two territories with OSHA-approved state plans are required to adopt standards at least as effective as federal OSHA standards but are not required to adopt or enforce general duty provisions. See generally *Gade* v. *National Solid Wastes Management Ass'n*, 112 S. Ct. 2374, 2382 (1992) (plurality opinion). The adoption of a federal OSHA standard therefore would provide more protection for employees in those jurisdictions. 56 Fed. Reg. 64,007.

the authority to issue mandatory health and safety standards, and Congress envisioned that specific standards that the agency develops through the rulemaking process would be the mainstay of OSHA regulation. S. Rep. No. 1282, 91st Cong., 2d Sess. 10 (1970) ("[t]he general duty clause in this bill would not be a general substitute for reliance on standards, but would simply enable the Secretary to [e]nsure the protection of employees who are working under special circumstances for which no standard has yet been adopted"); H.R. Rep. No. 1291, 91st Cong., 2d Sess. 21-22 (1970) ("th[e] [general duty] clause enables the Federal Government to provide for the protection of employees who are working under such unique circumstances that no standard has yet been enacted to cover this situation" (emphasis omitted)). See also *Usery* v. *Marquette Cement Mfg. Co.*, 568 F.2d 902, 905 n.5 (2d Cir. 1977). Congress envisioned the general duty clause as a supplement to, not a substitute for, mandatory standards.

Petitioner similarly errs in suggesting (Pet. 10-11) that OSHA should have analyzed the possible future reduction in risk of HBV that would result from Congress's passage of Pub. L. No. 102-141 requiring States, upon pain of losing certain federal funding, to issue guidelines consistent with CDC guidelines.[18]

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[18] Pub. L. No. 102-141, enacted on October 28, 1991, requires state public health officials, on pain of losing funds provided to their State under the Public Health Service Act, to issue, within one year of the law's enactment, guidelines covering health professionals practicing within their State which are equivalent to those promulgated by the CDC "concerning recommendations for preventing the transmission of [HIV] and [HBV] during exposure prone invasive procedures." Treasury,

Had OSHA awaited the development of epidemiological data reflecting the effects of possible changes on practices resulting from that law—which did not even require state compliance until a year after the law's passage, and which permitted States to obtain extensions from that deadline, see Pet. 5—promulgation of the bloodborne pathogens standard would have been delayed for years. Adoption of that approach would have put the agency on a collision course with Congress's subsequent mandate in Pub. L. No. 102-170 to issue by December 1, 1991, a bloodborne pathogens standard based on OSHA's proposed standard. OSHA, instead, acted properly and in conformance with Congress's mandates in Pub. L. No. 102-170 and the OSH Act itself by issuing a bloodborne pathogens standard based on "the best available evidence," 29 U.S.C. 655(b)(5)—the 1988 CDC epidemiological data and other record evidence from the rulemaking proceeding.[19]

Postal Service and General Government Appropriations Act, 1992, Pub. L. No. 102-141, § 633, 105 Stat. 876.

[19] Petitioner's reliance (Pet. 11) on this Court's decision in *Benzene* as support for its position is entirely misguided. In *Benzene*, the Court held that OSHA could not reduce the permissible exposure limit for a toxic substance, benzene vapor, without first showing that the existing exposure limit is unsafe. 448 U.S. at 644-645 (plurality opinion). OSHA complied with *Benzene* in this rulemaking by determining that there existed a significant risk of harm from occupational exposure to bloodborne pathogens. *Benzene* in no way suggests that there are any limitations on OSHA's authority to adopt a standard in lieu of a general duty clause enforcement policy, or that OSHA is required to account for the future effects of future state regulation of a hazardous substance.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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AUGUST 1993

No. 93-7

In The

Supreme Court of the United States

October Term, 1993

AMERICAN DENTAL ASSOCIATION,

Petitioner,

v.

ROBERT REICH, SECRETARY OF LABOR, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Seventh Circuit

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

I. The Court Should Grant The Petition To Resolve The Question Whether OSHA May Ignore The Most Cost-Effective Measures Capable Of Abating The Risk To Workers 2

II. The Court Should Grant The Petition To Resolve The Split In The Circuits Concerning OSHA's Authority To Combine Discrete Industry Groups And Toxic Agents When Determining Whether Workers Are Exposed To A Significant Risk. . . 5

III. The Court Should Grant The Petition To Clarify The Burden Of Proof And Standard Of Review In OSHA Rulemaking Proceedings, Which The Court Of Appeals Grossly Misapplied. 6

CONCLUSION 7

TABLE OF AUTHORITIES

Page

CASES

AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir. 1992) 5

American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 (1981) 2

Associated Builders & Contractors, Inc. v. Brock, 862 F.2d 63 (3rd Cir. 1988), *cert. denied* 490 U.S. 1064, 1065 (1989), and 494 U.S. 1003 (1990) 5

Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980) 3

International Union, UAW v. OSHA, 938 F.2d 1310 (D.C. Cir. 1991) 5

Jacobson v. Massachusetts, 197 U.S. 11 (1905) 4

Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29 (1983) 4

STATUTES

29 U.S.C. § 655(b) 4

29 U.S.C. § 655(b)(5) 4

Pub. L. No. 102-141, § 633, 105 Stat. 876 (1991) 2

Pub. L. No. 102-170, § 100(b), 105 Stat. 1113 (1991) 4

OTHER MATERIALS

56 Fed. Reg. 64,004 (1991) 3

58 Fed. Reg. 16,612 (1993) 4

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PETITIONER'S REPLY BRIEF

Respondents' arguments highlight why this Court should grant the petition. Respondents concede that the Court has not resolved one of the issues presented by the petition; that issue is ripe for resolution in this case. Respondents also acknowledge a split in the Circuits on another issue; that issue should likewise be resolved here.

Respondents do not even defend the bloodborne pathogens rule solely on OSHA's findings, which the Court of Appeals accepted in deference to OSHA. The rule, however, stands or falls on OSHA's findings that the hepatitis B virus presents a significant risk to workers

and that the requirements of the rule are necessary to protect workers from that virus. The rule cannot be sustained on that basis. The Court of Appeals grossly misapplied the standard of review by deferring to OSHA.[1]

I. The Court Should Grant The Petition To Resolve The Question Whether OSHA May Ignore The Most Cost-Effective Measures Capable Of Abating The Risk To Workers.

Respondents concede that this Court's decision in *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 513 n.32 (1981), reserved the question whether OSHA may ignore more cost-effective regulatory alternatives that would achieve a reduction in risk comparable to the standard adopted. Opp. 19. This case squarely raises that issue.

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[1] Respondents contend (Opp. 22-23) that the questions presented do not fairly include OSHA's failure to consider the law requiring the States to adopt and enforce the CDC guidelines for preventing transmission of HBV and HIV. Pub. L. No. 102-141, § 633, 105 Stat. 876 (1991). The ADA properly raised that fact in support of the first and second questions.

The first question focuses on the requirement that OSHA find a significant risk to workers before issuing a standard. Existing regulatory controls are an essential consideration when evaluating the risk to workers, particularly in this case because the law requiring States to enforce the CDC guidelines postdates the evidence on which OSHA based its finding that HBV presents a significant risk to workers. Pet. 10-11.

The second question focuses on whether OSHA may ignore more cost-effective alternatives to the standard adopted. That question fairly includes the ADA's argument that the most cost-effective remedy for HBV is State enforcement of the CDC guidelines combined with HBV vaccination. Pet. 13-14.

OSHA ignored the federal law requiring the States to enforce the CDC guidelines. In light of that law, OSHA should have adopted nothing more than a mandatory HBV vaccination program. Respondents do not dispute that a mandatory HBV- vaccination program, combined with State enforcement of the CDC guidelines, would be far more cost-effective than the final rule. Nonetheless, Respondents offer three justifications for OSHA's rejection of mandatory HBV vaccination.

First, Respondents note that "HBV vaccination is not entirely effective." Opp. 19. That argument misses the point, which is that vaccination is the most effective means of preventing the spread of HBV. OSHA found that the HBV vaccine is 96% effective. Pet. App. 91a. In contrast, OSHA concluded that the final rule would prevent only 87% of illnesses and deaths caused by hepatitis B. *See* 56 Fed. Reg. 64,004, 64,058/2 (1991).[2]

Second, Respondents state that "the workplace controls will provide substantial protection against infection by HIV and other bloodborne pathogens" besides HBV. Opp. 20. That justification is improper because OSHA did not find that pathogens other than HBV pose a significant risk to workers. Pet. App. 93a; *see Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 642-43

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[2] The 87% efficacy rating is based on an assumption that only 50% of workers subject to the rule will voluntarily take the HBV vaccine. 56 Fed. Reg. at 64,057/3.

The residual risk after HBV vaccination is insignificant. According to OSHA's estimates, a vaccinated health care worker's annual risk of hospitalization due to HBV is one in 200,000 and the annual risk of death is one in 500,000. Pet. 7 n.6.

(1980). In any event, compliance with the CDC guidelines will protect workers from pathogens other than HBV.

Third, Respondents argue that OSHA made a policy choice to allow workers to reject the vaccine "for medical, religious, or other reasons." Opp. 20. Respondents ignore this Court's holding in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), that mandatory vaccination programs do not violate the Constitution.

Respondents' arguments concerning OSHA's failure to consider the mandatory CDC guidelines (Opp. 24-25) are improper post-hoc rationalizations. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 50 (1983). Respondents cannot repair OSHA's error with new arguments on appeal.[3]

Recently, the Department of Labor concluded that the Occupational Safety and Health Act requires OSHA, when promulgating an occupational safety standard under section 6(b), 29 U.S.C. § 655(b), to adopt "the most cost-effective protective measures capable of reducing or eliminating significant risk." *See* 58 Fed. Reg. 16,612, 16,614/3 (1993). The same principle should apply when, as in this case, OSHA issues an occupational health standard under section 6(b)(5), 29 U.S.C. § 655(b)(5).

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[3] The congressional mandate that OSHA adopt a bloodborne pathogens rule (Pub. L. No. 102-170, § 100, 105 Stat. 1113) has no effect on this case. Congress ordered OSHA to adopt a rule, *not this rule*. The congressional mandate does not change the standard of review. *Cf. Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 45 (even unequivocal congressional ratification – short of statutory incorporation – would not change the standard of review for agency action).

II. The Court Should Grant The Petition To Resolve The Split In The Circuits Concerning OSHA's Authority To Combine Discrete Industry Groups And Toxic Agents When Determining Whether Workers Are Exposed To A Significant Risk.

By citing *Associated Builders & Contractors, Inc. v. Brock*, 862 F.2d 63, 68 (3d Cir. 1988), *cert. denied*, 490 U.S. 1064, 1065 (1989), and 494 U.S. 1003 (1990), Respondents confirm the split among the Circuits concerning OSHA's authority to make a universal assessment of the risks presented by numerous physical agents to workers in divergent industries. The *Associated Builders* opinion, like the Court of Appeals' majority opinion in this case, cannot be squared with the decisions in *AFL-CIO v. OSHA*, 965 F.2d 962 (11th Cir. 1992), and *International Union, UAW v. OSHA*, 938 F.2d 1310 (D.C. Cir. 1991). This issue will recur in future OSHA rulemaking proceedings. The Court should grant the ADA's petition to resolve the issue.[4]

By attempting to distinguish the Eleventh Circuit's decision in *AFL-CIO v. OSHA*, 965 F.2d at 962, Respondents support the ADA's argument (Pet. 11-12) that

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[4] Respondents contend that OSHA gave specific consideration to the risks in dental settings, citing evidence concerning dental health care workers' risk of acquiring hepatitis B. Opp. 7 n.6. That evidence predates the CDC guidelines and does not take into consideration increasing use of the HBV vaccine, which was not available until the early 1980s.

Respondents also quote OSHA's unsupported assertion that dental health care workers "are continually exposed to blood and bloody saliva during almost all dental procedures." Opp. 7. Uncontradicted evidence in the record demonstrates that nearly half of all patient visits expose dental health care workers to saliva without blood. Record Ex. 58.

OSHA improperly lumped together HBV, HIV, and other pathogens for purposes of evaluating the risk to workers. Respondents correctly describe the Eleventh Circuit's holding "that OSHA, in promulgating a multi-substance standard, had not adequately demonstrated significant risk for each substance." Opp. 17. That holding also applies to this rulemaking, in which OSHA did not find that HIV, syphilis, or any pathogen other than HBV posed a significant risk to workers.

Respondents concede that OSHA designed the blood-borne pathogens rule to protect workers from all pathogens. Opp. 2. That is why OSHA required workers who have been vaccinated against HBV to wear personal protective equipment, use care in the handling of laundry and waste, etc. App. 94a. Those requirements cannot be justified by the insignificant residual risk to vaccinated workers.

III. The Court Should Grant The Petition To Clarify The Burden Of Proof And Standard Of Review In OSHA Rulemaking Proceedings, Which The Court Of Appeals Grossly Misapplied.

Respondents defend the Court of Appeals' majority opinion by arguing that OSHA's findings are entitled to deference when they involve issues on the frontier of scientific knowledge. Opp. 21. The majority opinion, however, identified errors that have nothing to do with science, such as OSHA's failure to consider the adverse impact the final rule will have on patient care. Pet. App. 6a, 9a-10a. Each time the majority opinion identified an error by OSHA, the majority deferred to OSHA because

the ADA did not "quantify" the magnitude of OSHA's mistakes. *Id.* That approach improperly shifts the burden of proof to industry and dilutes the standard of review to the point that it is virtually meaningless.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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